UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GEORGE ASSAD, Derivatively on Behalf of FIBROGEN, INC., Plaintiff, v. ENRIQUE CONTERNO, PAT COTRONEO, CHRISTINE CHUNG, MARK EISNER, JAMES A. SCHOENECK, K. PEONY YU, SUZANNE BLAUG, AOIFE BRENNAN, BENJAMIN F. CRAVATT, JEFFREY L. EDWARDS, JEFFREY W. HENDERSON, MAYKIN HO, THOMAS F. KEARNS JR., GERALD LEMA, RORY B. RIGGS, and KALEVI KURKIJÄRVI, Individual Defendants, -and- FIBROGEN, INC., a Delaware corporation, Nominal Defendant.	Case No. 1:21-cv-01811-RGA

AMENDED VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff George Assad ("Plaintiff"), by his attorneys, submits this amended verified stockholder derivative complaint for the benefit of nominal defendant, FibroGen, Inc. ("FibroGen" or the "Company"), against its Board of Directors (the

"Board") and certain of its executive officers for violations of securities laws, breaches of fiduciary duties, insider trading (*Brophy* claim), and unjust enrichment. Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based upon, among other things, the investigation conducted by and through Plaintiff's attorneys, which included the review and analysis of: (a) documents and information obtained pursuant to 8 *Del. C.* § 220 ("Section 220") (the "220 Demand"); (b) public filings made by FibroGen and other related parties and non-parties with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (c) press releases and other publications disseminated by the certain of the Defendants (defined herein) and other related non-parties; (d) the pleadings and responsive filings in the related securities class action captioned *In re FibroGen, Inc. Securities Litigation.*, Case No. 3:21-cv-02623-EMC (N.D. Cal.) (the "Securities Class Action"); and (e) other publicly available information concerning FibroGen and Defendants.

NATURE AND SUMMARY OF THE ACTION

1. FibroGen is a pharmaceutical company that develops and commercializes drugs to treat anemia, fibrotic disease, and cancer. At all relevant times, the Company's lead product candidate was Roxadustat, an oral treatment for anemia in patients with chronic kidney disease ("CKD"). Substantially all of the Company's revenue was derived from collaboration agreements through which

FibroGen received "milestone" payments for achieving development and regulatory goals to commercialize Roxadustat.

2. The standard of care, Epogen[1], increases the risk of major adverse cardiac events ("MACE"),[2] so it is not recommended for use in less severe CKD cases, including non-dialysis dependent ("NDD") and new-to-dialysis patients ("incident dialysis" patients). A significant drawback of Epogen is that these safety risks required a "black box" warning alerting patients and prescribers that the drug increases the risk of death, serious cardiac events, thrombosis, and tumors, among other serious risks. Roxadustat purportedly presented an advantage over Epogen in two respects: (1) it is allegedly an easily administered oral treatment; and (2) it was purportedly safe for use by both NDD and incident dialysis patients.

3. To support an application for regulatory approval from the U.S. Food and Drug Administration ("FDA"), the Company sought to show that Roxadustat was as safe as Epogen and did not require a "black box" warning. Specifically, FibroGen's clinical trials sought to show that Roxadustat was "non-inferior" relative to the relevant comparator (Epogen or placebo) in all three patient populations: NDD, incident dialysis, and dialysis dependent ("DD").

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[1] *See* epogen.com.

[2] MACE is a composite measure of serious cardiovascular events, including stroke, myocardial infarction, and cardiovascular death.

4. Beginning in December 2018, the Company touted the positive results observed during Roxadustat's Phase 3 clinical studies. Not only did the drug show the "potential to bring clinical benefit over current standard of care," the "pooled" safety results purportedly demonstrated that Roxadustat was safer than Epogen and placebo.

5. On November 8, 2019, FibroGen announced that, based on an analysis "agreed [upon] with the FDA" using "a reference non-inferiority margin of 1.3," the hazard ratios used to measure the safety of the drug was below 1.3 for all three patient populations. The Individual Defendants (as defined herein) touted these results as "show[ing] a very positive benefit-risk profile for the product" and that they "don't believe that the data that we have warrants a [Black Box] warning."

6. FibroGen's Board has no committee that is responsible for the oversight of data integrity in the Company's clinical trials. The Board appears to have never evaluated or even discussed controls over data integrity or whether the data it was reviewing, and that was being publicly disclosed, was produced using the prespecified analyses agreed upon with the FDA.

7. In November 2019, two reports were issued by separate self-described *short sellers* questioning whether Roxadustat was in fact safe and whether the publicly reported data was derived using the prespecified analyses agreed upon with the FDA. The Company vigorously and publicly disputed the allegations. The

Board, however, never looked into them or even sought to assure itself that any process or controls were in place to ensure that the reported data was the result of the analyses agreed upon with the FDA.

8. On December 23, 2019, FibroGen announced that it had submitted Roxadustat's New Drug Application ("NDA") to the FDA, marking a regulatory milestone for which the Company received $50 million from AstraZeneca. The NDA was scheduled for a December 20, 2020 final review date pursuant to the Prescription Drug User Fee Act ("PDUFA").

9. However, in mid-November 2020, a Citizen Petition was filed with the FDA urging the agency to decline the Roxadustat NDA because, among other things, the safety data reported on November 8, 2019 improperly "disguised" significant safety concerns and the data was not generated using the analyses agreed upon with the FDA.

10. The Board again did not look into the allegations or even seek to assure itself that a process existed that would alert it if the data was not being analyzed as agreed upon with the FDA or if the allegations were true. The Board also did not review the Company's rebuttal to the Citizen's Petition prior to issuance.

11. Later that same month, FibroGen announced the "retirement" of its Chief Medical Officer, K. Peony Yu, M.D. Yu had overseen the development of Roxadustat for many years and the submission of the NDA. It was highly suspicious

for her to leave the Company so close to the PDUFA date when FibroGen anticipated regulatory approval, especially since she did not actually retire and instead took a position at another company just three months later. The Board did not discuss Yu's departure before it occurred and did not inform itself as to the reasons for her retirement after the fact. Nor did the Board review her separation agreement, before or after it was executed, and the Company did not publicly disclose the separation agreement either.

12. Then, on December 18, 2020, FibroGen announced that the FDA extended the review period by three months and requested additional data analyses. Even though short sellers and a Citizen's Petition had questioned whether the data was produced using the prespecified analyses agreed upon with the FDA, the architect of the trials, Yu, had mysteriously "retired" on the doorstep of obtaining approval for Roxadustat, and now the FDA was extending the review period, the Board did not seek to assure itself of the quality of the data, nor did it seek to confirm that a process was in place to alert if there were data integrity problems. Nonetheless, management publicly sought to downplay the significance of the delay, claiming the additional data was merely "analyses of existing Roxadustat clinical data."

13. Then, on March 1, 2021, the FDA notified the Company it would hold an Advisory Committee meeting to review the NDA.

14. On March 29, 2021, Defendant Yu – who had announced her surprise retirement in November – engaged in conduct that must be considered evidence of both her culpability and that the Company knew the FDA would reject the Roxadustat NDA.

15. According to Yu's deposition and other discovery in the Securities Class Action, on March 29, 2021, Defendant Yu intentionally and completely destroyed the hard drive on her Company-issued laptop. She did this knowing full well that litigation against the Company was imminent given that she knew Roxadustat's data had been manipulated and failed to satisfy the requisite safety protocols.

16. Based on information from discovery in the Securities Class Action (much of which remains redacted), on March 29, 2021, Yu took her laptop to a local vendor called NerdsToGo, located near her home in Bellevue, WA, and directed a technician to replace the laptop's hard drive with a new one and then destroy the old hard drive by breaking it into pieces and discarding it in a garbage can. Yu has admitted under oath that no data from the hard drive was preserved and that she neither backed it up nor instructed the vendor to back up the hard drive before breaking it into pieces.

17. Egregious as this was, Yu went even further in destroying evidence that Roxadustat was a failure, and it was known to the most senior people at the

Company. She instructed the technician at NerdsToGo to place a new, working hard drive (that was the "exact same" as the old hard drive) in the laptop before she shipped it back to the Company. She further instructed the technician to install a new operating system on the hard drive, presumably to erase any possible information that could be recovered from a chip or other mechanism. Incredulously, she testified in the Securities Class Action that that she believed the Company urgently wanted the laptop back due to a computer chip shortage.

18. It also came to light during discovery in the Securities Class Action that certain defendants in that case shredded all of Yu's hard copy documents in mid-March 2021.

19. The truth began to emerge on April 6, 2021, a mere eight days after Yu destroyed her laptop and her documents were shredded, when FibroGen announced that the safety data previously presented to investors "included post-hoc changes to the stratification factors." In other words, as Yu knew when she destroyed her laptop, the data presented to the FDA had not been produced using the prespecified analyses the FDA had agreed to when the trial was designed. The Company now re-reported the results using the proper pre-specified analysis and noted that "based on these analyses ***we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen]***."

20. The Company's public statements issued during the previous two years extolling the safety benefits of Roxadustat and claiming that it was superior to the standard of care were false. An article by the American Society of Nephrology stated "the net effect" of the "statistical shenanigans" was "to remove [R]oxadustat's evident safety advantage compared with the drugs it would presumably replace."

21. An article in pharmaceutical news outlet *Evaluate Vantage* stated "FibroGen's staggering admission" "stretches the bounds of credibility," and defendants would "struggle to shake suspicions" regarding their role in the "sorry debacle."

22. Biotechnology publication, *STAT+*, stated: "the company has been touting false heart safety data [] for at least two years—a shocking revelation." *STAT+* described the conduct as the "worst case of data manipulation in years," stating that "FibroGen cheated." *STAT+* further asked, "how can anyone – investors, physicians, regulators – trust [a] company that spent nearly two years touting cardiovascular safety data that turns out to have been falsified?"

23. The major pharmaceutical and biotechnology publication, *FiercePharma*, stated the "data doctoring" was a "stunning revelation":

> FibroGen admitted to presenting roxadustat data manipulated to make the anemia drug look safer than it is… [t]he fact that all nine analyses across the patient groups looked less favorable for [R]oxadustat after the change raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better.

24. Making matters that much worse, the manipulated data had been submitted ***to the FDA*** with Roxadustat's NDA. FibroGen stated it would "promptly . . . clarify this issue with the FDA." The submission of study data to the FDA that had been improperly manipulated post hoc in an effort to obtain approval of a drug that was not warranted virtually guaranteed rejection of the Roxadustat NDA.

25. On July 15, 2021, a briefing document released in advance of the Advisory Committee meeting revealed that the FDA had mandated critical prespecified "sensitivity" analyses. The prespecified sensitivity analyses showed that the hazard ratio exceeded the FDA's goal of 1.25 for each of the relevant endpoints for NDD and DD patients. As a result, the FDA concluded that Roxadustat's "benefits are difficult to calculate here" and that the drug posed numerous safety risks.

26. As the Advisory Committee concluded, FibroGen's own undisclosed, prespecified sensitivity analyses of Roxadustat demonstrated that the drug's efficacy over Epogen was inconclusive at best, and the drug caused "greater rates of some important adverse events [] than even [Epogen]," including a higher rate of death and other major side effects. As a result, the Advisory Committee voted virtually unanimously against approval for Roxadustat for any patient population, even with a "Black Box" warning.

27. Unsurprisingly, on August 11, 2021, FibroGen announced receipt of a Complete Response Letter from the FDA confirming that the Roxadustat NDA would not be approved for any patient population.

28. Plaintiff did not make a litigation demand prior to filing this action because such a demand would have been futile. When this action was initiated, the Board was composed of eleven members, all of whom are named in this Action. As alleged herein, the Board had no process in place to oversee the integrity of data reported in the Roxadustat clinical trials and did not ever seek to assure itself that the data being publicly reported and submitted to the FDA was produced using the analyses agreed to by the FDA. In the face of red flags expressly and implicitly raising questions about the same, the Board took no action. Relatedly, the Board permitted the widespread dissemination of corporate lies about the safety and efficacy of Roxadustat and the chances for FDA approval of the drug. Thus, the majority of the Board faces a substantial likelihood of liability and demand is excused.

JURISDICTION AND VENUE

29. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise federal questions under Section 14(a) of the Exchange Act, 15 U.S.C. §78n(a)(1), Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, and Section 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a) and

78t-1). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

30. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that would not otherwise have such jurisdiction.

31. Venue is proper in this District because FibroGen is incorporated in this District, and the Defendants' activities have had an effect in this District.

THE PARTIES

Plaintiff

32. Plaintiff George Assad is and has continuously been a stockholder of FibroGen during the wrongdoing complained of herein.

Nominal Defendant

33. Nominal Defendant FibroGen is a Delaware corporation with its principal executive offices located at 409 Illinois Street, San Francisco, CA 94158. Its common stock trades on the NASDAQ exchange under the symbol "FGEN."

The Individual Defendants

34. Defendant Enrique Conterno ("Conterno") has served as Chief Executive Officer ("CEO") of FibroGen and as a director since January 6, 2020. He is named as a defendant in the Securities Class Action.

35. Defendant James Schoeneck ("Schnoeneck") has served as Chair of the Board of Directors of the Company since January 2020 and as a director since April 2010. He also served as interim CEO of FibroGen from August 2019 to January

2020. He is named as a defendant in the Securities Class Action. He was a member of the Audit Committee during fiscal years 2018 and 2019. During the relevant period, Defendant Schoeneck made the following sales of FibroGen stock on the basis of material, non-public information:

Date	**Shares Sold**	**Price**	**Proceeds**
Jan. 7, 2019	2,000	$45.90	$91,800
Feb. 7, 2019	2,000	$57.17	$114,340
Mar. 7, 2019	1,620	$54.62	$88,484
Mar. 7, 2019	380	$55.23	$20,987
Apr. 8, 2019	2,000	$52.90	$105,800
May 7, 2019	1,500	$46.80	$70,200
May 7, 2019	500	$47.69	$23,845
		TOTAL PROCEEDS:	**$515,456**

36. Defendant K. Peony Yu ("Yu") served as Chief Medical Officer ("CMO") of FibroGen from April 2016 to December 2020. Prior to that, she served as VP of Clinical Development for FibroGen for eight years. She is named as a defendant in the Securities Class Action. For fiscal 2019, she also "received an additional special RSU award" of 20,000 shares valued at $1,146,600 in recognition of, among other things, "increasing leadership role[] to attain the following critical corporate goals: completion of roxadustat Phase 3 studies in the U.S. and Europe and obtaining market approval of roxadustat in China." Moreover, under the 2019 Bonus Plan, defendant "Yu had her bonus paid at 107.4% of her target level with her individual goal achievement at 117%," including "her efforts in the completion

of the roxadustat pooled MACE safety data analyses[and] the roxadustat New Drug Application submission to the U.S. Food and Drug Administration," and received a cash bonus payment of $316,830. During the relevant period, Defendant Yu made the following sales of FibroGen stock on the basis of material, non-public information:

Date	**Shares Sold**	**Price**	**Proceeds**
Mar. 14, 2019	9,145	$56.30	$514,864
June 14, 2019	3,420	$40.96	$140,083
Sep. 16, 2019	3,419	$40.92	$139,905
Dec. 16, 2019	3,420	$46.68	$159,646
July 24, 2020	3,351	$42.35	$141,915
Sep. 3, 2020	10,000	$50.89	$508,900
Sep. 16, 2020	3,351	$44.01	$147,478
Dec. 16, 2020	3,350	$41.61	$139,394
		TOTAL PROCEEDS:	**$1,892,184**

37. Yu took affirmative steps to destroy information on her laptop concerning Roxadustat's trials. She took these actions on March 29, 2021, just days before the Company announced on April 6, 2021 that data had not been produced using the prespecified analyses the FDA had agreed to when the trial was designed. The Company ultimately re-reported the results using the proper pre-specified analysis and noted that "based on these analyses *we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen].*"

38. Defendant Mark Eisner ("Eisner") has served as the CMO of FibroGen since December 2020. He is named as a defendant in the Securities Class Action.

39. Defendant Pat Cotroneo ("Cotroneo") served as the Chief Financial Officer ("CFO") of FibroGen from 2008 to September 6, 2021. He is named as a defendant in the Securities Class Action. During the relevant period, Defendant Cotroneo made the following sales of FibroGen stock on the basis of material, non-public information:

Date	**Shares Sold**	**Price**	**Proceeds**
Feb. 28, 2019	14,787	$60.07	$888,255
Mar. 19, 2019	7,665	$55.41	$424,717
June 18, 2019	3,201	$43.12	$138,027
Sep. 17, 2019	3,201	$41.38	$132,457
Dec. 20, 2019	46,727	$45.51	$2,126,545
Dec. 20, 2019	12,729	$46.27	$588,970
Mar. 16, 2020	9,239	$26.36	$243,540
June 16, 2020	3,928	$39.68	$155,863
Aug. 7, 2020	22,554	$48	$1,082,592
Sep. 3, 2020	15,004	$50.91	$763,853
Sep. 15, 2020	3,070	$43.63	$133,944
Dec. 15, 2020	3,068	$43.60	$133,764
June 15, 2021	4,053	$25.62	$103,837
		TOTAL PROCEEDS:	**$6,916,369**

40. Defendant Christine Chung ("Chung") has been Senior Vice President of China Operations at FibroGen since 2007. During the relevant period, Defendant Chung made the following sales of stock on the basis of material, non-public information:

Date	Shares Sold	Price	Proceeds
May 7, 2019	1,925	$46.04	$88,627
May 7, 2019	3,500	$46.70	$163,450
May 7, 2019	200	$47.44	$9,488
May 8, 2019	4,125	$46.20	$190,575
May 8, 2019	1,500	$46.62	$69,930
June 18, 2019	5,625	$44.08	$247,950
June 19, 2019	5,625	$44.02	$247,612
July 10, 2019	5,025	$44.75	$224,868
July 10, 2019	600	$45.14	$27,084
July 11, 2019	5,525	$45.13	$249,343
July 11, 2019	100	$45.72	$4,572
Aug. 22, 2019	5,325	$43.79	$233,181
Aug. 22, 2019	300	$44.67	$13,401
Aug. 23, 2019	3,225	$42.05	$135,611
Aug. 23, 2019	1,816	$42.94	$77,979
Aug. 23, 2019	584	$43.68	$25,509
Sep. 19, 2019	2,225	$40	$89,000
Sep. 19, 2019	3,400	$40.75	$138,550
Sep. 20, 2019	5,625	$39.87	$224,268
Oct. 8, 2019	3,225	$36.55	$117,873
Oct. 8, 2019	2,400	$37.10	$89,040
Oct. 9, 2019	5,625	$36.58	$205,762
Nov. 13, 2019	5,625	$34.54	$194,287
Nov. 14, 2019	3,600	$34.50	$124,200
Nov. 14, 2019	2,025	$35.18	$71,239
Dec. 16, 2019	2,850	$46.80	$133,380
Dec. 16, 2019	2,775	$47.37	$131,451
Dec. 17, 2019	5,336	$46.95	$250,525
Dec. 17, 2019	289	$47.47	$13,718
Jan. 6, 2020	5,625	$42.98	$241,762
Jan. 7, 2020	5,625	$42.76	$240,525
Feb. 11, 2020	5,625	$44.48	$250,200
Feb. 12, 2020	5,025	$45.94	$230,848
Feb. 12, 2020	600	$46.28	$27,768
Mar. 18, 2020	905	$23.69	$21,439
Mar. 18, 2020	1,500	$24.56	$36,840
Mar. 18, 2020	1,500	$25.68	$38,520
Mar. 19, 2020	300	$23.93	$7,179

Mar. 19, 2020	830	$25.32	$21,015
Mar. 19, 2020	6,215	$26.08	$162,087
		TOTAL PROCEEDS:	**$5,070,665**

41. Defendant Suzanne Blaug ("Blaug") has served as a director of FibroGen since June 2019.

42. Defendant Aoife Brennan ("Brennan") has served as a director of FibroGen since August 2020.

43. Defendant Benjamin F. Cravatt ("Cravatt") has served as a director of FibroGen since August 2020.

44. Defendant Jeffrey L. Edwards ("Edwards") has served as a director of FibroGen since 2015. He was Chair of the Audit Committee at all relevant times.

45. Defendant Jeffrey W. Henderson ("Henderson") has served as a director of FibroGen since August 2015.

46. Defendant Maykin Ho ("Ho") has served as a director of FibroGen since December 2018 and as a member of the Audit Committee since June 2019.

47. Defendant Thomas F. Kearns, Jr. ("Kearns") has served as a director of FibroGen since November 1996.

Date	**Shares Sold**	**Price**	**Proceeds**
Mar. 19, 2020	18,000	$23.17	$417,060
Mar. 11, 2021	18,000	$35.02	$630,360
		TOTAL PROCEEDS:	**$1,047,420**

48. Defendant Gerald Lema ("Lema") has served as a director of FibroGen since September 2017. He has been a member of the Audit Committee since August 26, 2019.

49. Defendant Rory B. Riggs ("Riggs") has served as a director of FibroGen since October 1993.

50. Defendant Kalevi Kurkijärvi ("Kurkijärvi") served as a director of FibroGen from November 1996 to June 30, 2021. He was a member of the Audit Committee until September 5, 2019. During the relevant period, Defendant Kurkijärvi made the following sales of FibroGen stock on the basis of material, non-public information:

Date	**Shares Sold**	**Price**	**Proceeds**
Apr. 8, 2019	3,427	$52.95	$181,460
Apr. 8, 2019	573	$53.51	$30,661
Apr. 15, 2019	4,000	$48.09	$192,360
May 8, 2019	5,056	$45.83	$231,716
May 8, 2019	944	$46.51	$43,905
June 6, 2019	2,942	$37.20	$109,442
June 6, 2019	3,058	$38.49	$117,702
July 8, 2019	4,600	$42.35	$194,810
July 8, 2019	1,400	$43.40	$60,760
Aug. 5, 2019	6,000	$45.22	$271,320
Sep. 9, 2019	5,580	$40.90	$228,222
Sep. 9, 2019	420	$41.67	$17,501
Oct. 7, 2019	6,000	$36.73	$220,380
Nov. 7, 2019	4,514	$38.08	$171,893
Nov. 7, 2019	1,486	$38.85	$57,731
Dec. 9, 2019	6,000	$47.50	$285,000
Jan. 6, 2020	6,000	$42.66	$255,960
Feb. 10, 2020	6,000	$42.69	$256,140

Dec. 28, 2020	5,901	$40.39	$238,341
Dec. 28, 2020	100	$41.14	$4,114
Jan. 14, 2021	5,999	$40.04	$240,200
Jan. 19, 2021	6,000	$43.38	$260,280
Feb. 17, 2021	5,156	$52.31	$269,710
Feb. 17, 2021	844	$52.93	$44,673
		TOTAL PROCEEDS:	**$3,984,284**

51. Defendants Conterno, Schoeneck, Yu, Eisner, Cotroneo, Chung, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi are collectively referred to hereinafter as the "Individual Defendants."

Relevant Non-Parties

52. Thomas B. Neff ("Neff") founded FibroGen in 1993 and served as its Chairman and CEO until his death on August 25, 2019.

SUBSTANTIVE ALLEGATIONS

Roxadustat Was FibroGen's Lead Product Candidate

53. FibroGen is a pharmaceutical company that develops and commercializes drugs to treat anemia, fibrotic disease, and cancer. At all relevant times, the Company's lead product candidate was Roxadustat, an oral treatment for anemia in patients with CKD. Unlike other anemia drugs on the market, Roxadustat works as a hypoxia-inducible factor prolyl hydroxylase ("HIF-PH") which stimulates the body's natural red cell production.

54. CKD is a progressive disease whereby the gradual loss of kidney function leads to kidney failure or end-stage renal disease, requiring dialysis or a

kidney transplant. Anemia is a common complication of CKD that causes severe fatigue and reduces quality of life, and it is associated with an increased risk of death.

55. The standard of care for anemia in CKD patients is a drug called Epogen, or epoetin alfa, which is an erythropoiesis-stimulating agent ("ESA"). It is administered by injection or intravenously, so patients must visit a doctor or hospital to receive the treatment. Moreover, Epogen increases the risk of MACE, so it is not recommended for use in less severe CKD cases, including NDD and incident dialysis patients. A significant drawback of Epogen is that these safety risks required a "black box" warning that it increases the risk of death, serious cardiac events, thrombosis, and tumors, among other serious risks.

56. Roxadustat presented an advantage over Epogen, the standard of care, in two respects: (1) it is an oral treatment, so it could be easily administered; and (2) it was purportedly safe for use by NDD and incident dialysis patients. According to the Company, Roxadustat was "an oral agent with a potentially more favorable safety profile" than Epogen, so it would "expand the market for anemia treatment by penetrating the NDD-CKD market," which was "substantially larger" than the dialysis-dependent ("DD") market. Many analysts estimated that the total addressable market for Roxadustat was approximately $3.5 billion.

57. Roxadustat was developed in collaboration with AstraZeneca AB ("AstraZeneca"), a biopharmaceutical company. According to the 2013 agreement

with AstraZeneca, FibroGen would be primarily responsible for the development of the drug and the analysis of critical clinical data, while AstraZeneca would cover the costs of development and provide "milestone" payments as development and regulatory goals were met. These potential milestone payments totaled nearly $1.2 billion, of which $571 million was for "development and regulatory milestones" and $652.5 million was for "commercial-based milestones."

58. At all relevant times, FibroGen recognized revenue primarily from its collaboration agreement with AstraZeneca for Roxadustat.

To Obtain Regulatory Approval, FibroGen Conducted Clinical Trials for Roxadustat

59. To obtain regulatory approval from the FDA for commercializing a drug, a pharmaceutical company must conduct three trials sufficient to evaluate whether the benefits (or efficacy) outweigh its negative side effects (safety). There are three phases: (1) Phase 1 evaluates safety, including adverse events and proper dosage; (2) Phase 2 primarily evaluates efficacy and is used to determine the optimal dosage; and (3) Phase 3 demonstrates the efficacy, optimal dosage, and safety across thousands of patients.

60. FibroGen's goal was to show that Roxadustat was not only as safe as Epogen, but also that it did not require a "black box" warning. Neff stated that the goal of the trials was to show that Roxadustat was "non-inferior" relative to the relevant comparator (*i.e.*, Epogen or placebo) in all three patient populations.

61. The Phase 3 trial for Roxadustat involved over 9,000 CKD patients across three key patient populations (DD, NDD, and incident dialysis patients). The studies were randomized, double-blind studies, so neither the researcher nor the patient knew whether they received the placebo, Epogen, or Roxadustat.

62. To demonstrate that Roxadustat did not cause more adverse safety events than the placebo or Epogen, FibroGen used three safety endpoints: (1) MACE, a metric the FDA primarily evaluated for anemia treatments; (2) all-cause mortality, or "ACM," which measured deaths caused by Roxadustat; and (3) MACE+, a composite endpoint that included all MACE events, in addition to hospitalizations. MACE+ was the primary focus of European regulatory authorities. The three patient populations across these three endpoints produced nine separate analyses, *i.e.*, MACE, ACM, and MACE+ for each of the three patients populations.

63. These three safety endpoints were measured using a "hazard ratio," which compared the time until an adverse safety endpoint occurred for patients taking Roxadustat to that for patients taking Epogen or the placebo. For example, a hazard ratio of 0.5 means that, for a given period, half as many patients taking Roxadustat experienced an adverse safety event compared to those taking Epogen or placebo. If the hazard ratio was below 1.0, the FDA could conclude that Roxadustat was safer than Epogen in DD/incident dialysis patients or the placebo in

NDD patients. However, if the hazard ratio was above 1.25, then Roxadustat would be deemed too unsafe for any patient population, regardless of a label warning.

The Individual Defendants Caused FibroGen to Tout That Roxadustat was More Effective and Safer Than EpoGen and as Safe as the Placebo

64. On December 20, 2018, the Individual Defendants caused FibroGen to issue a press release announcing the much-anticipated top line results for the Phase 3 trial for Roxadustat, in which the Company touted the safety and efficacy results. Specifically, defendant Yu stated that Roxadustat had "achieved superiority in efficacy not only against placebo but also over active comparator [Epogen] in our studies," which "support[s] [R]oxadustat's potential to bring clinical benefit over current standard of care." It also noted that "in the pre-specified secondary efficacy analysis, Roxadustat-treated patients had a 33% reduction in the risk of blood transfusion compared to [Epogen]."

65. Though the Company would not issue the "pooled" safety results until the next year, the December 20, 2018 press release stated that "preliminary safety analyses of each of [the Phase 3] individual studies show an overall safety profile consistent with the results observed in previous Roxadustat studies." That is, the safety results from earlier phases of clinical studies were purportedly demonstrated across the much larger sample size of 9,000 patients.

66. These results were repeated during FibroGen's conference call on February 27, 2019 regarding the Company's fourth quarter and full year 2018

financial results. Specifically, Neff stated that all of the Phase 3 studies "have positive top line results" and "based on our review of the data . . . there is a strong conviction to move ahead to file the NDA." Defendant Yu also highlighted that it was of "much clinical importance" that "Roxadustat was [] shown to have a lower [red blood cell] transfusion risk than ESA." Moreover, defendant Yu stated that the Company was "encouraged by the robust efficacy results, and the preliminary safety data in individual Phase 3 studies and the ongoing pool efficacy and safety analyses."

67. On March 15, 2019, defendants Edwards, Henderson, Ho, Kearns, Kurkijärvi, Lema, Riggs, and Schoeneck attended a Board meeting where they discussed "an update on the Company's and its partners' progress on Phase 3 data analysis and the plan for FDA interactions." FGEN_220_0000015.[3] According to the presentation reviewed at this meeting, "Data from studies for the pooled MACE/MACE+ analyses will be unblinded at the same time, 2Q, 2019," and preparation was ongoing. FGEN_220_0000023. The Board was told that FibroGen was "responsible for data integration & preparation of key documents." *Id*.

68. On May 2, 2019, defendants Cotroneo, Edwards, Schoeneck, and Kurkijärvi attended an Audit Committee meeting where they discussed the Company's disclosures regarding the Phase 3 trial data. *See* FGEN_220_0000051-

[3] Citations to "FGEN_220_#######" refer to documents produced in response to Plaintiff's 220 Demand.

55. Notably, the meeting materials demonstrate that the directors did not review the actual pooled results. *See* FGEN_220_0000039-55. Nor did they solicit or receive any information regarding the processes and procedures used to produce the data. *See id*. Similarly, from late 2018 through the release of the data, the directors conducted no oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed.[4]

69. The pooled safety results were announced on May 9, 2019. Pursuant to FibroGen's discussions with the FDA, the safety data was combined ("pooled") across all studies in the Phase 3 trials. The Individual Defendants caused FibroGen to issue a press release claiming that, based on an intention to treat ("ITT") analysis purportedly discussed with the FDA, there was "no clinically meaningful difference" in MACE risk between the two treatment arms for DD and NDD patients (*i.e.*, between Roxadustat and Epogen/placebo). Moreover, Roxadustat had purportedly achieved "[s]uperiority in time to first MACE+ versus [Epogen] in incident dialysis patients" with a "trend toward reduced [MACE] risk for patients on [R]oxadustat" compared to Epogen. In the same press release, defendant Yu was quoted as saying

[4] Plaintiff's books and records demand sought, among other things, any Board materials reflecting "[i]nternal controls governing the integrity of clinical data," and such documents were within the scope of production agreement with FibroGen. However, none of the approximately 1,000 pages produced even confirm the existence of such controls, let alone demonstrate that the Board was overseeing them.

that FibroGen is "particularly excited about the results indicating a reduction of risk of MACE+ events in incident dialysis patients."

70. Also on May 9, 2019, FibroGen held a conference call, during which Neff reiterated that "the message there is we're trending favorably" and FibroGen was moving forward with its NDA. He specifically pointed to the topline results which were "strongly supportive of the efficacy and safety of Roxadustat" and that there were "***fewer [safety] events in Roxa versus [Epogen]***" across "every one" of the MACE+ categories, including deaths, myocardial infarctions, strokes, unstable angina hospitalizations, and congestive heart failures resulting in hospitalizations.[5] As a result, Roxadustat presented a "statistically significant advantage over" Epogen.

71. During the same call, defendant Yu reiterated that under the purportedly "conservative" ITT analysis, FibroGen was "able to show non-inferiority to placebo," which was "the gold standard for safety" and "***really illustrates the strength of our drug's safety***." She also stated that "***we are superior in time to MACE+ analysis in incident dialysis***" patients, meaning that "the upper bound of the 90% confidence interval is less than 1" such that "when you compare the hazard between Roxadustat to that of [Epogen], we have a very significant p value."

[5] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

72. Critically, the ITT analysis used for the topline results were purportedly discussed with the FDA and was the standard non-inferiority analysis used by the FDA. During the May 9, 2019 conference call, defendant Yu assured that the ITT analysis was the "safety evaluation standard the FDA usually asks for" to establish non-inferiority and that a hazard "ratio of below 1.3" was the "standard non-inferiority comparison" used to evaluate MACE results. She went on to state that Roxadustat "achieved non-inferiority" under these standards:

> [W]e are using the conventional standards of noninferiority, which is widely published for assessment of chronic kidney disease anemia and have previously been used by [the FDA] for assessment of cardiovascular safety in similar types of composite endpoints . . . that standard has been 1.3 for upper bound of 95% confidence interval. ***If we use that standard, the answer is yes, we have achieved non-inferiority.***

73. When analysts on the call asked whether FibroGen could avoid the dreaded black box warning on Roxadustat's label based on the MACE safety data, defendant Yu responded: "[B]ased on what we have seen, we are pretty comfortable with safety. The adjudicated composite safety endpoint was something that we have discussed with the FDA."

74. Although the Individual Defendants touted the purported safety of Roxadustat, they had not announced specific hazard ratios, which concerned stockholders who could not confirm that Roxadustat had achieved statistical non-

inferiority to placebo or Epogen. As a result, the Company's stock price fell $9.28, or 20%, to close at $36.39 per share on May 10, 2019.

75. Management quickly met with analysts to assuage these concerns, telling a Jeffries analyst that "[t]he Company feels very confident about Roxa's numerically lower [MACE] event rate profile." In fact, the Individual Defendants had not confirmed statistical non-inferiority because FibroGen purportedly had not yet reached a "statistical agreement [with the FDA] on upper and lower bounds" for the MACE hazard ratios.

76. On June 5, 2019, the Board met and discussed the pooled safety data. Defendants Cotroneo, Yu, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *See* FGEN_220_0000056. Defendant "Yu provided a summary of the roxadustat Phase 3 pooled cardiovascular safety analysis," and the "Board discussed the data and the status with the FDA." FGEN_220_0000058. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000056-80. Nor do the meeting materials reflect that the directors conducted any oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000081-90.

77. The Individual Defendants continued to tout the safety and efficacy of Roxadustat at multiple conferences before the detailed MACE safety data was released. For example, at the Goldman Sachs 40th Annual Global Healthcare Conference held on June 12, 2019, defendant Yu stated that FibroGen had "compelling evidence confirming [R]oxadustat's cardiovascular safety to support our regulatory filings" and that "MACE results in dialysis and non-dialysis also support the conclusion of no increased cardiovascular safety risk." She "emphasize[d] [the] MACE+ superiority in [the] incident dialysis pool" as well as the "efficacy benefits," such as "transfusion reduction" and "improvement in quality of life." Neff claimed that, armed with these results, FibroGen was "in a place now where we ***have safety data and efficacy data that's superior to [Epogen]*** in a U.S. setting."

78. Not only did the results "open[] the door to Roxa being recommended as a first medicine," Neff claimed at the June 12 conference that the MACE data suggested Roxadustat "shouldn't have a 'Black Box'" warning:

> [A] key goal in the U.S. was—with chronic kidney disease population, a placebo study was to show non-inferior to placebo, to show that there isn't any incremental risk measure so that opens the door to the logic [that Roxadustat] shouldn't have a 'Black Box' for placebo. Therefore ***Roxa should not have a 'Black Box'*** and go from there in dealing with dialysis. ***And it's turned out as we hoped for.***

79. On July 25, 2019, defendants Cotroneo, Yu, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi met and discussed "the

upcoming work in preparing the NDA, the MAA, interactions with the NMPA and other ongoing and upcoming work streams for the management team." FGEN_220_0000091. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000091-92.

80. On August 1, 2019, the Audit Committee convened a meeting to review and approve the second quarter 2019 financial results. Defendants Cotroneo, Schoeneck, Edwards, and Ho were present. *See* FGEN_220_0000105. They also specifically discussed the Company's disclosures regarding the Phase 3 results, including "the process involved with preparing the MACE data and disclosure presentation in the coming week." FGEN_220_0000106. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000105-08. Nor do the meeting materials reflect that the directors conducted any oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000093-104.

81. On August 2, 2019, the Board met to discuss FibroGen's pre-NDA meeting with the FDA. *See* FGEN_220_0000109. Defendants Cotroneo, Schoeneck, Yu, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *See id*. Specifically, defendant "Yu provided a summary of the Pre-NDA Meeting

on July 30, 2019 regarding the NDA submission for roxadustat in CKD anemia, expected later this year." *Id*. The meeting attendees "discussed the outcome of that meeting." *Id*. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See id*.

82. To support the NDA, FibroGen would have to show that Roxadustat was safe and effective using analyses with which the FDA agreed. On August 8, 2019, FibroGen held a conference call in connection with its second quarter 2019 financial results, during which Neff assured that the Company had "reached an agreement with the [FDA] on the content of the NDA including the cardiovascular safety analysis." Defendant Yu stated FibroGen had a "very good re-NDA meeting with the FDA" at which they reached an agreement "on our proposed pooled MACE analysis," which had been announced to stockholders on May 9, 2019. Defendant Yu also claimed that as a result of this agreement, the Company's "level of confidence is very high, and we do believe . . . that our Phase 3 results confirm cardiovascular safety of [R]oxadustat in the chronic kidney disease population in both dialysis and non-dialysis."

83. On September 5, 2019, the Board convened a meeting where they discussed, among other things, an update on the Roxadustat programs. *See* FGEN_220_0000110-16. Defendants Cotroneo, Schoeneck, Blaug, Edwards,

Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *See* FGEN_220_0000110. The meeting minutes state, in relevant part:

> 11. Roxadustat Update. Dr. Yu provided an update of the roxadustat programs including a successful pre-NDA meeting with the FDA with ***an agreement on pooling strategy and analysis methods for non-dialysis and dialysis***. Dr. Yu noted that we submitted two late breaking abstracts for ASN this week. Dr. Yu provided a detailed review of NDA submission work that is on track for submission in October 2019, and a target for MAA submission by Astellas in January 2020. The Board asked about harmonization of pricing across territories and Ms. Tsuboi discussed ongoing efforts regarding pricing. ***Dr. Yu noted which presentations we expect to be presented by investigators at ASN on the first week of November.*** Dr. Yu noted that we revised the page insert for China roxadustat after we received non-dialysis approval. She also provided an update on regulatory discussions in China, in which the company provided a summary of the U.S. MACE and MACE+ data.
>
> All participants left the meeting other than the Board of Directors, Mr. Lowenstein, Mr. Alden and Dr. Yu.
>
> ***Dr. Yu presented more detailed results from the pooled MACE and MACE+ studies.***

FGEN_220_0000113.

84. The presentation for the September 5, 2019 reflects that the meeting attendees were informed, for the first time, of the FDA's requirement to perform "sensitivity analysis" 28 days after treatment. *See* FGEN_220_0000120. It also informed the Board that FibroGen had not reached an agreement with the FDA regarding the appropriate non-inferiority margin, noting that the analyses led to certain conclusions "***if*** usual & [customary] NI margin 1.3 applies." *Id*. Specifically, in a slide titled "FDA Pre-NDA Meeting July 30, 2019," the Board noted that

FibroGen "[g]ained clarifications on analyses & green light from FDA to submit NDA" and stated:

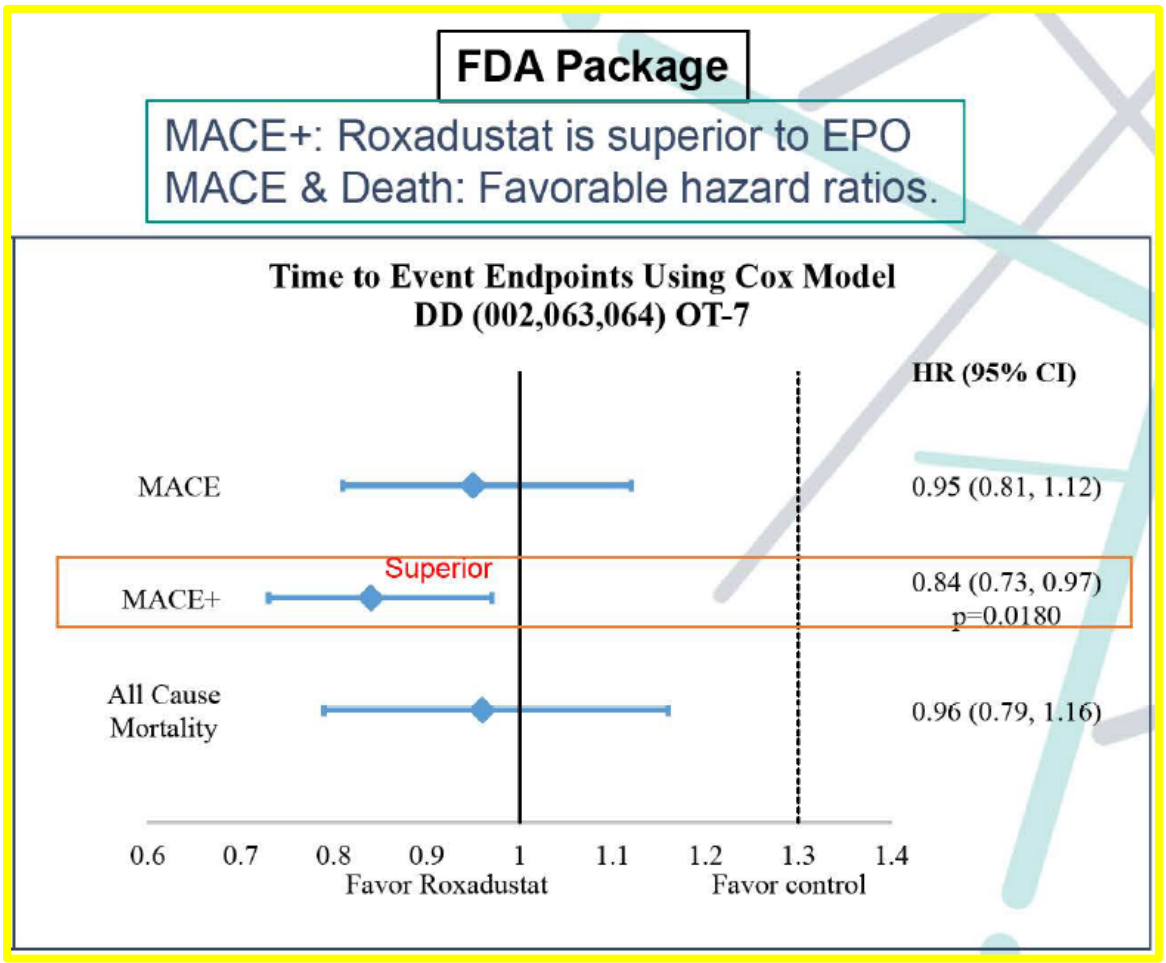
- **Dialysis**: All Dialysis DD & Incident Dialysis ID
  - Agreement on pooling 3 studies (exclude AST 613) for CV safety endpoint & Phase 3 integration for ISS [FGN 063, FGN 064, AZ 002]
  - OT-7 for primary analysis + ***OT-28 for sensitivity analysis***
  - Implications: Scientifically sensible & most favorable MACE and MACE+ results in comparing roxadustat to [Epogen]
    - DD: MACE non-inferior; MACE+ superior
    - ID: MACE superior; MACE+ superior
- **Nondialysis** CKD
  - Agreement on the studies being pooled: FGN 060, AST 608, AZ 001
  - MACE primary endpoint- FDA accepted proposal for ITT analysis [long term followup, include on-treatment & off-treatment period until common study end date]
  - ***Implications: MACE & MACE+ noninferiority to placebo (if usual & customary NI margin 1.3 applies)***

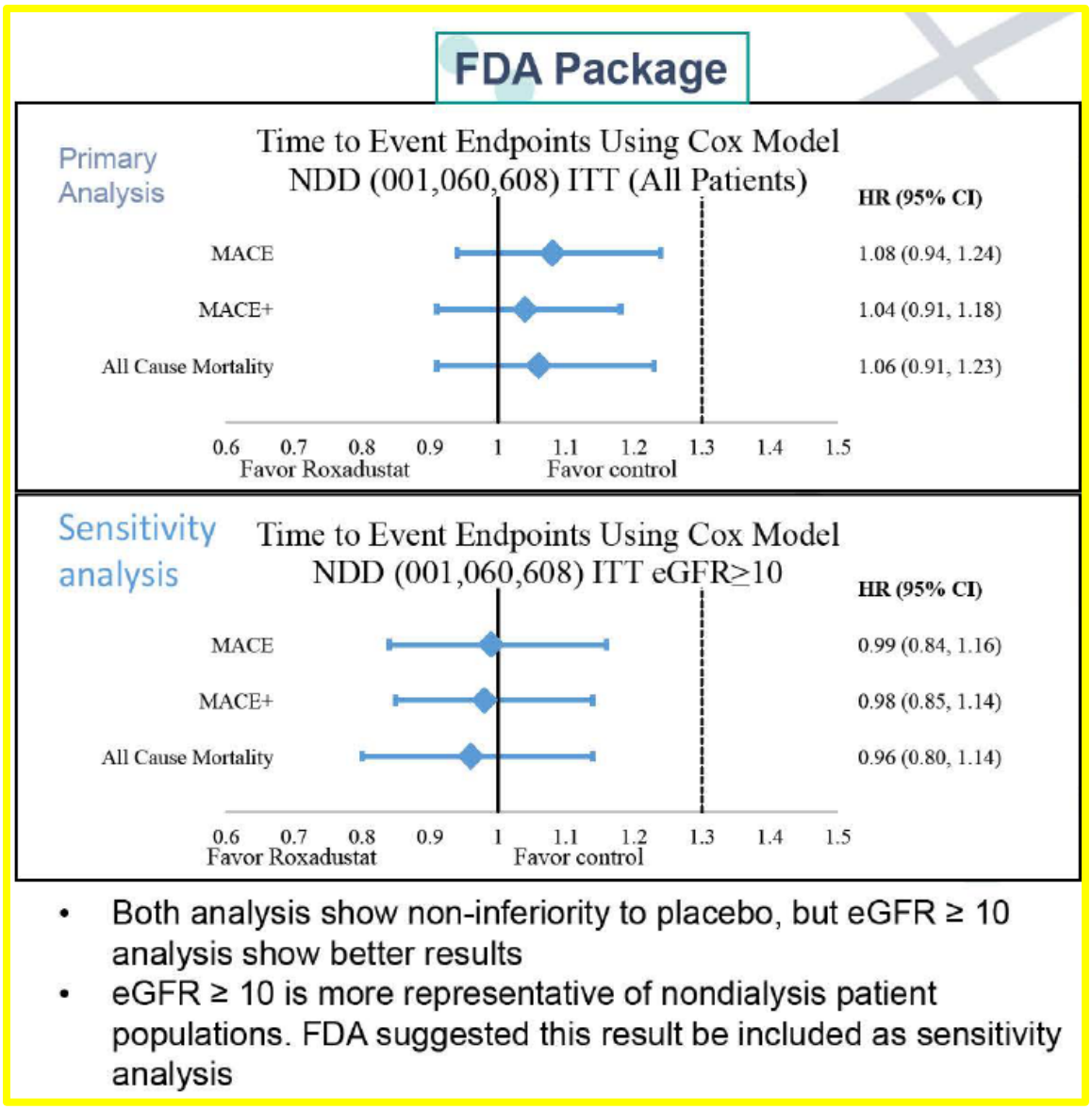
Id.

85. The September 5, 2019 presentation also showed the hazard ratios across patient populations. Specifically, defendants Cotroneo, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi reviewed and discussed data results purportedly showing that, for incident dialysis patients,

"Roxadustat Significantly Lowers MACE+ Hazard by 34%, Compared to [Epogen]" and "Roxadustat Significantly Lowers Hazard of MACE by 30% Compared to [Epogen]." FGEN_220_0000133. For incident dialysis patients, the hazard ratio for MACE+ was 0.66 on average with a lower bound of 0.50 and upper bound of 0.89, for MACE was 0.70 on average with a lower bound of 0.51 and upper bound of 0.97. *See id*.

86. They also discussed the following results that would be submitted as part of the "FDA package," including a sensitivity analysis:





FGEN_220_0000136-37.

87. At the September 5, 2019 meeting, the Board also discussed the "Draft US Package Insert," including the hazard ratios that would be publicly reported two months later. *See* FGEN_220_0000163-69.

88. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See*

FGEN_220_0000110-16. Nor do the meeting materials reflect that the directors conducted any oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000117-37.

89. On November 4, 2019, a short seller, Plainview Capital LLC, issued a short report questioning the safety data FibroGen had disclosed for Roxadustat and whether the data was derived pursuant to analyses that were agreed upon with the FDA.

90. The MACE hazard ratios were announced to stockholders and the investing public in November 2019. In a press release issued on November 8, 2019, the Individual Defendants caused FibroGen to announce the safety and efficacy results that had been presented at the American Society of Nephrology Kidney Week 2019. Therein, FibroGen stated that "Roxadustat cardiovascular safety [was] comparable to placebo in [NDD] patients," which no other anemia drug had shown before. Moreover, Roxadustat "did not increase risk of MACE and reduced risk of MACE+ compared to [Epogen]" in DD patients, while it also "reduced risk of MACE by 30% and MACE+ by 34% compared to [Epogen]" by a statistically significant margin in the crucial incident dialysis patient population.

91. The November 8, 2019 press release falsely stated that the positive Roxadustat MACE results the Company had presented were the result of the prespecified analyses they had "***agreed [upon] with the FDA.***"

92. On November 11, 2019, FibroGen held a conference call in connection with its third quarter 2019 financial results, during which defendants Schoeneck and Yu repeated many of the statements from the November 8, 2019 press release regarding Roxadustat's safety and efficacy. In the face of "investor concern about FDA agreements and FDA sign-off," defendant Yu had "no concern" about the MACE hazard ratios, stating:

> [W]e had already talked with the FDA about [the] analytical plan, and we had made the agreement on the analysis plan. The results that we have presented in the high-impact clinical session at the ASN, and the numbers I had just presented, ***were based on the agreed analysis plan that we have made with the FDA.***

93. On November 12, 2019, defendants Cotroneo, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema, and Riggs met and received an "Investor Relations/Corporate Communications Update." FGEN_220_0000158. Even though the Plainview Capital LLC short report had been issued approximately a week earlier and Yu, on behalf of the Company, had issued statements purporting to rebut it, during the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000158-59.

94. On November 12, 2019, the Individual Defendants caused FibroGen to file with the SEC the Company's Form 10-Q for Q3 2019, which was signed and certified by Schoeneck and Cotroneo. The 10-Q stated the "cardiovascular safety analysis reflects the pooling strategy and analytical approach we agreed on with the FDA." The 10-Q also stated that in FibroGen's "pre-NDA meeting, the FDA agreed that the ITT-analysis would be our primary cardiovascular safety analysis method for non-dialysis in the U.S. as it uses on-treatment and post-treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm."

95. In an email published on November 14, 2019, in response to a separate short seller report by BuyersStrike that also questioned whether Roxadustat's data reflected FDA required analyses, FibroGen stated: "We do not agree with this report … The data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA."

96. On December 23, 2019, FibroGen announced that it had submitted the NDA for Roxadustat to the FDA, marking a regulatory milestone for which the Company received $50 million from AstraZeneca. The NDA was scheduled for a final review date under the Prescription Drug User Fee Act ("PDUFA") for December 20, 2020.

97. While the NDA was under review by the FDA, the Individual Defendants continued to tout the purported safety and efficacy of Roxadustat. On February 25, 2020 at the SVB Leerink Global Healthcare Conference, defendant Conterno stated that "the [Roxadustat] data that we have on cardiovascular safety is very compelling" and the data is "extremely clean." He touted that the safety data was "highly compelling" because it had been shown "against what I think is a very high hurdle of placebo" in every single MACE category. As a result, defendant Conterno stated that "I do not believe that the data warrants a 'Black Box'" warning.

98. On March 2, 2020, the Individual Defendants caused the Company to file with the SEC FibroGen's 2019 Form 10-K, signed by Conterno, Cotroneo, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Kurkijärvi, Lema, Riggs, Rosenkranz, and Tamura. The Form 10-K reproduced the previously disclosed clinical trial results and stated that the cardiovascular safety analyses "reflect the pooling strategy and analytical approach we agreed on with the FDA." The Form 10-K further represented that: "In our pre-NDA meeting, the FDA agreed that the intent-to-treat analyses followed for long-term safety results would be our primary cardiovascular safety analysis method for non-dialysis in the U.S. as it uses on-treatment and post treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm."

99. Also on March 2, 2020, FibroGen held a conference call in connection with its fourth quarter and full year 2019 financial results. During the call, defendant Yu claimed that Roxadustat was potentially better than the current standard of care because of "the robust efficacy and safety profile demonstrated," including that it "demonstrated a meaningful reduction in cardiovascular safety risk, as Roxadustat-treated incident dialysis patients had a 30% lower MACE risk and a 34% lower MACE+ risk than [Epogen]-treated patients."

100. On April 4, 2020, the Board issued FibroGen's definitive proxy statement soliciting votes on several proposals in advance of the Company's June 4, 2020 annual meeting of shareholders. According to the proxy statement, the Compensation Committee of the Board considered "key achievements" of certain executive officers in awarding incentive compensation under the 2019 Bonus Plan. In particular, "Dr. Yu was recognized for her efforts in the completion of the roxadustat pooled MACE safety data analyses, the roxadustat New Drug Application submission to the U.S. Food and Drug Administration" and "Dr. Kouchakji was recognized for his efforts in support of the review and interpretation of global safety data including MACE analyses for the Phase 3 roxadustat program." Based on the foregoing, "Dr. Kouchakji had his bonus paid at 106.4% of his target level, with his individual goal achievement at 112%; and Dr. Yu had her bonus paid at 107.4% of her target level with her individual goal achievement at 117%." On the basis of these

supposed achievements, Kouchakji and Yu were awarded total compensation for 2019 of $4.9 million and $5.8 million, respectively.

101. Defendant Yu repeated the March 2, 2020 statements during the May 7, 2020 conference call held in connection with the first quarter 2020 financial results. She further stated:

> [I]n conclusion, Roxadustat, excellent cardiovascular safety profile, coupled with the statistically significant and clinically meaningful, higher hemoglobin efficacy results and lower transfusion rate relative to epoetin alfa, together makes Roxadustat potentially a better treatment option for dialysis-dependent patients. ***We like the hand that we have and expect the product label to reflect the results of clinical trials on our compound.***

102. On May 14, 2020, FibroGen participated in the Bank of America Securities 2020 Health Care Conference. During the conference, defendant Conterno stated that the Company must "highlight the incident dialysis data, whereby we basically show a reduction in risk of MACE events at a time that is critical" because "[t]his is the time when a treatment decision is made when it comes to anemia." He emphasized that "clearly the data is . . . highly differentiated" from Roxadustat's competitors.

103. On April 6, April 23, and May 14, 2020, defendants Schoeneck, Conterno, Blaug, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi attended Board meetings where they discussed an update on the status of the NDA interactions with the FDA. *See* FGEN_220_0000240-41; FGEN_220_0000242-44;

FGEN_220_0000257-59. The minutes and materials from the April 6, April 23, and May 14, 2020 meeting contain no indication that the Board solicited or received any information regarding the processes and procedures used to produce the data. *See id*.

104. On June 4, 2020, defendants Schoeneck, Conterno, Blaug, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi attended a Board meeting. *See* FGEN_220_0000260. Defendant Yu "gave an update on the regulatory interactions with US FDA," and the "Board asked a variety of questions regarding the regulatory process, including the potential for an advisory committee meeting potential outcomes with respect to the label, differentiators for roxadustat versus competitors, and development pathways for additional indications." *Id*. The accompanying meeting materials reflect that they also discussed that FibroGen had received "4 new requests [since] 4/21/20: regarding the source of epoetin alfa in the DD Phase 3 studies, explanation regarding the differences in TEAE between Ex US and US, and provide the analysis of death due to AEs by Hb level groups, by region (US vs Ex-US) for DD and NDD populations." FGEN_220_0000297. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000260-94. Nor do the meeting materials reflect that the directors conducted any oversight over the

Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000295-313.

105. On June 9, 2020, FibroGen participated in the Goldman Sachs 41st Annual Global Healthcare Conference where defendant Conterno again emphasized the "huge" and "compelling" results in the incident dialysis population:

> [A]s I think you know, I've been very excited about our incident dialysis data and the fact that ***we showed a 30% reduction in MACE risk and 34% when it comes to MACE+. Honestly, that's huge and that's an anchor.*** Because as patients start dialysis, clearly part of that dialysis initiation is going to be treatment of anemia. And ***I believe that we have the very best data. It's quite compelling and differentiated.***

106. At the same conference, he stated that "given that [FibroGen] showed [Roxadustat had] basically comparable safety to placebo" – which was "very difficult to achieve" – the Company had "the very best chance basically to have a label without a 'Black Box.'"

107. On July 7, 2020, the Board convened a meeting to discuss, among other things, FibroGen's mid-cycle review meeting with the FDA. *See* FGEN_220_0000314. Defendants Schoeneck, Conterno, Blaug, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *See id*. They discussed "feedback from the agency regarding the product, the discussions in the meeting, and the progress that had been made, including the plan to initiate label discussions in the third quarter, the possibility of an advisory committee meeting, and a risk evaluation and management strategy for the product." *Id*. During the meeting, the Board did not

solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000314-15.

108. On July 29, 2020, the Board met and discussed "the takeaways from the Company's FDA mid-cycle meeting for the roxadustat NDA." FGEN_220_0000316-17. Defendants Schoeneck, Conterno, Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs were present. *See* FGEN_220_0000316. Moreover, defendant "Yu then provided details on the proposed approach to address the items coming out of the meeting." FGEN_220_0000317. Specifically, the accompanying meeting materials indicate that the Board reviewed and discussed the following "Highlights from the FDA Meeting":

- No Major Safety Concerns identified, therefore no REMS
- FDA requested a PRO Dossier to support the roxadustat PRO label claims
- No Advisory Committee meeting
- FDA stated that roxadustat was consistently non-inferior and not superior to ESA. ***Therefore the FDA believed the Warnings and Precautions would be reflected in the same way as ESA's including the Black Box Warning.***
- We reminded FDA of the Incident Dialysis population and the superior CV safety profile that had been demonstrated to ESA in a more "*level playing field*", where patients started on the medications at the same time
- We also discussed our data in NDD against placebo showing no increased CV risk.

- FDA (Dr. Unger) agreed to consider our arguments during their review

FGEN_220_0000319.

109. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000316-17. Nor do the meeting materials reflect that the directors conducted any oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000318-57.

110. On August 6, 2020, FibroGen held a conference call with investors during which defendant Conterno stated that "We continue to view that our data shows a very positive benefit-risk profile for the product" and that "our engagement and our interaction with the FDA was positive, so we feel good about the progress that we are making." None of the Company's August 6, 2020 disclosures informed investors that notwithstanding the foregoing, the Individual Defendants had been specifically informed that the FDA believed that a "black box" warning would be necessary. *See* FGEN_220_0000319.

111. On September 9, 2020, FibroGen participated in the Citigroup 15th Annual BioPharma Conference. The previous week, FibroGen's competitor anemia drug, Vadadustat, had failed to show non-inferiority in the non-dialysis dependent group compared to ESAs due to its hazard ratio above ***1.25***, which the Individual

Defendants knew or should have known was the hazard ratio by which Roxadustat would be measured. When an analyst asked how Roxadustat's data should be viewed in light of the competitor's negative safety results, defendant Conterno cited "the significant level of evidence that we have already with Roxadustat around NDD" and that the Company "was able to show non-inferiority relative to placebo, which is a higher bar than a comparison to a product that had [or has] box warnings." As a result, he reiterated that "we ***feel very good about our pool MACE data in NDD***" such that "***we don't believe that the data that we have warrants a [Black Box] warning.***" None of the Company's September 9, 2020 disclosures informed investors that, notwithstanding the Individual Defendants' purported belief that the Roxadustat data did not warrant a "black box" warning, they had been specifically informed that the FDA believed such a warning would be necessary. *See* FGEN_220_0000319.

112. On September 15, 2020, defendants Schoeneck, Conterno, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi met and discussed "the progress in the U.S. NDA filing, including the overall timeline, most recent feedback from the FDA, the elements of the draft label that were under discussion." FGEN_220_0000368-69. Among other highlights, the accompanying meeting materials reflect that the Board discussed that the "Black Box Warning [was] Requested by FDA, but they didn't impose the ESA Box

Warning" and that the agency "[t]ook out the pooled ID data as they stated it was a subgroup of dialysis." FGEN_220_0000378. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000368-74. Nor do the meeting materials reflect that the directors conducted any oversight over the Company's processes for clinical data management, programming, analysis or reporting, if any formal processes existed. *See* FGEN_220_0000375-97.

113. On October 26, 2020, defendants Schoeneck, Conterno, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Lema, and Riggs met and discussed the "analyst call following the ASN conference, and the concerns and focus of analysts, including the potential impact of competitor data which had failed to meet the safety endpoint in the non-dialysis population." FGEN_220_0000398. They also discussed "the difference between the clinical programs and the types of analyses performed." *Id*.

114. At the October 26, 2020 meeting, the Board also discussed "an update on interactions with the U.S. FDA, and key elements of discussions surrounding the potential roxadustat package insert, including a box warning, transfusion data, dosing algorithm, and incident dialysis data." FGEN_220_0000399. They also discussed "the characterization of the product by the FDA, the most important elements of the label as it relates to commercialization, and how this might position

the product with respect to competition." *Id*. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000398-99.

115. On November 5, 2020, FibroGen held a conference call with investors during which defendant Conterno stated that "I think what's important is when – first, when we look at the overall trial, we basically see that in non-dialysis dependent, we were comparable to placebo. So that's when it comes to MACE. So that's critically important. ***We showed non-inferiority.***" Moreover, he stated that "in incident dialysis, the excellent data that we have with – showing basically reduced cardiovascular outcomes in this population, so that's extremely important." None of the Company's November 5, 2020 disclosures informed investors that notwithstanding purportedly showing "non-inferiority" and "reduced cardiovascular outcomes" in incident dialysis patients, the Individual Defendants specifically knew that the FDA believed that a "black box" warning would be necessary. *See* FGEN_220_0000319.

116. On November 17, 2020, FibroGen participated at the Stifel 2020 Virtual Healthcare Conference where analysts wondered whether it was a positive sign that the FDA never convened an Advisory Committee ("AdCom") to review the Roxadustat NDA. Defendant Conterno relied on the "very compelling" data the Company had submitted, stating:

> Given the chance of an FDA Advisory Committee Meeting, we had to prepare for one but that's really water under the bridge. . . . ***At this stage, I think what I can say is basically we have to rely on the data that we've shared.*** And I feel that the data that we shared, I think is very compelling when it comes to Roxadustat…the broad safety data that we have first thing in dialysis-dependent where we look at both our safety data there when we compare to ESAs. As you know we had pretty compelling data when it comes to incident dialysis we had statistics in terms of a reduction in the number of MACE events in that setting. And then when we look at NDD, we were compared to placebo and we basically had comparability when it comes to overall safety. So, feel very good about the overall package that we had . . . ***Clearly we've already said and have demonstrated both the efficacy and the safety of the product.***

117. On November 18, 2020, FibroGen participated at the Jefferies Virtual London Healthcare Conference. Defendant Conterno emphasized that "Clearly, we have a high level of conviction on the overall submission, the strength of our data" and that "Clearly, I think the – when we look at our data, we continue to feel that the data basically offers a very favorable risk-benefit profile for patients across the continuum."

The Truth Begins to Emerge When FDA Unexpectedly Convenes an AdCom Meeting for the NDA, but the Individual Defendants Continue to Tout Roxadustat's Purported Superiority

118. In mid-November 2020, an FDA Citizen Petition was filed urging the FDA to decline the Roxadustat NDA pending additional data demonstrating that the benefits outweigh the risks. It also requested a "black box" warning indicating that the MACE risks was similar to that of Epogen, alleging that the presentation of the

safety data at the November 8, 2019 conference had improperly "disguised" significant safety concerns.

119. Then, on November 27, 2020, the Company announced the abrupt "retirement" of defendant Yu. Her exit, when FibroGen was allegedly on the eve of regulatory approval for its key drug after years of development, was highly suspicious. Moreover, she did not stay "retired." She took a position as Chief Medical Officer at another company just three months later—a position she still appears to hold today.

120. In Form 8-K filed on December 1, 2020, the Company disclosed that:

> As part of this transition, on November 27, 2020 FibroGen entered into a Transition, Separation, and Consulting Agreement with Dr. Yu (the "Agreement") which provides for Dr. Yu to remain as a Company employee to assist with the transition to Dr. Eisner until March 15, 2021, at which time she will enter into a consulting agreement for a period of six months with the Company to provide services related to development, regulatory and commercialization matters with respect to the Company's products.
>
> Under the Agreement, and contingent upon, among other things, delivery of releases of claims at various points in time, in addition to the severance benefits set forth in Section 3(b) of her Change in Control Severance Agreement that she would be entitled to under a qualifying termination, Dr. Yu will receive: an increase in the bonus payment to 150% of Dr. Yu's target bonus amount for 2020 pursuant to the Company's 2020 Bonus Plan as the sole bonus payment to be received; a consulting agreement for up to eight hours per week following the termination of employment with the Company, the consideration for which will be continued vesting of outstanding stock options and other equity awards ("Stock Awards") during the consulting term; and the right to exercise any outstanding Stock Awards after the termination of

> services to the Company until the date that is one year following the termination of services to the Company.

121. Notably, the Company did not publicly file the Transition, Separation, and Consulting agreement with Yu. Board materials reflect that the Board neither reviewed the agreement prior to its execution, nor inquired into or was informed of any information related to the reasons for or terms of Yu's "retirement" afterward.

122. On December 9, 2020, the Company sent a letter to the FDA rebutting the claims in the Citizen Petition. This letter was neither reviewed by the Board beforehand or after it was sent, and Board materials contain no evidence that Board even discussed the points raised in the letter. In the letter, signed by Senior Vice President Frost, the Company asserted that Roxadustat had demonstrated "non-inferiority compared to [Epogen], and in the NDD-CKD pool, Roxadustat demonstrated non-inferiority to placebo with respect to MACE." Regarding the Citizen Petition's accusation that the NDA did not contain accurate and complete data, the letter falsely stated that the NDA submission was "complete and transparent":

> FibroGen's NDA submission was complete, complied with all FDA guidance, and included data from all clinical and preclinical studies. The Integrated Summary of Safety cardiovascular safety report includes the pooled cardiovascular safety analyses of the DD-CKD, and NDD-CKD patient populations. In addition, for completeness and full transparency, FibroGen included certain cardiovascular safety sensitivity analyses, including the stable dialysis subgroup, and the DD-CKD pool including the PYRENEES study. The results from these sensitivity analyses do not change the conclusions with respect to

> MACE of non-inferiority of roxadustat to epoetin-alfa in DD-CKD patients, and non-inferiority of Roxadustat to placebo in NDD-CKD patients. In conclusion, FibroGen's NDA submission was complete and transparent. The data supporting the safety and effectiveness of roxadustat is robust and compelling.

123. On December 18, 2020, the Board met to discuss FibroGen's "recent interactions with the FDA." FGEN_220_0000431. Defendants Schoeneck, Conterno, Blaug, Brennan, Cravatt, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *See id*. During the Company's late stage label negotiations, the FDA sent additional requests for data, including "additional analyses of roxadustat safety data," and indicated that the agency's "review of such analyses would extend beyond the current December 20, 2020 PDUFA date."[6] *Id*. During the meeting, the Board did not solicit or receive any information regarding the processes and procedures used to produce the data. *See* FGEN_220_0000431-32.

124. On December 18, 2020, FibroGen announced that the FDA had extended the review period for the Roxadustat NDA by three months. Such a delay was concerning "especially considering how late it came in the review cycle,"

[6] The Board received another update about the resubmitted data during a meeting on February 1, 2021, including the FDA's requests for data analyses. *See* FGEN_220_0000433-34. On February 26, 2021, the Board discussed that "there was a potential for the FDA to hold an advisory committee meeting," and that "there was a lack of clarity as to the FDA's intent as well as the FDA's acknowledgement that not all analyses had yet been performed in the course of their review." FGEN_220_0000435-36.

according to analysts, and the agency's request for "new data analyses could very likely translate to higher risk (otherwise, why weren't they included in the original filing?)." Thus, on this news, the Company's stock price fell $3.96, or 9%, to close at $40.01 per share on December 21, 2020.

125. On March 1, 2021, the Individual Defendants caused the Company to file with the SEC FibroGen's 2020 Form 10-K, signed by Conterno, Cotroneo, Schoeneck, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Kurkijärvi, Lema, and Riggs. The Form 10-K reproduced the previously disclosed clinical trial results and stated that the cardiovascular safety analyses "reflect the pooling strategy and analytical approach we agreed on with the FDA."

126. FibroGen suffered another setback when the FDA notified the Company it would hold an AdCom meeting to review the NDA. This news, which was revealed to the market on March 1, 2021, caused the Company's stock price to fall $16.18, or 32%, to close at $34.35 per share on March 3, 2021.

127. During a conference call on March 1, 2021, the Individual Defendants dismissed concerns that the AdCom meeting signaled a possible "black box" warning, even though they knew that the FDA had previously indicated its belief that a "black box" warning would be necessary. Specifically, defendant Conterno stated that FibroGen "continue[d] to have confidence in the completeness of the NDA submission and the strength of the Roxadustat data" and that "Clearly, the

efficacy and safety of Roxadustat were established by the global Phase 3 programs." Similarly, defendant Eisner stated that FibroGen was "very confident in our data for both [NDD and DD] populations." Defendant Conterno also touted the false safety results, stating "of course, the data that we have on incident dialysis, we believe, is some of the strongest data[,] [a]s we think about MACE and MACE+ significance in that population."

128. On March 2, 2021, at the 41st Annual Cowen Healthcare Conference, defendant Conterno again downplayed the significance of the AdCom meeting. He considered the AdCom meeting "an opportunity to basically showcase, I think, the strength of our data, and we continue to have confidence on the strength of the data on Roxadustat across both [DD] and NDD." The totality of the data "supports – the benefit-risk profile," adding "I know because we've discussed in the past, and I think I've been pretty clear in terms of what has been agreed with the FDA and what hasn't been agreed with the FDA. I think that's known."

129. However, on April 6, 2021, stockholders were shocked to learn that the data that the Individual Defendants were "confident" about had been manipulated. In a press release, FibroGen stated that the safety data presented to investors "included post-hoc changes to the stratification factors," including changes to "the cut point for GFR [which measures kidney function] based on hemoglobin" and

"additional variables of sex, race and body mass index," all of which would distort the significance of the underlying data.

130. Post hoc analyses are inherently improper because they are selective analyses conducted in hindsight pursuant to cherry-picked criteria that are determined after all data is collected and fully unblinded. According to the FDA's guidance, post hoc analysis is considered "data-dredging" designed to "elicit a positive study result from a failed study," leading to "biased" results:

> In the past, it was not uncommon, after the study was unblinded and analyzed, to see a variety of post hoc adjustments of design features (e.g. endpoints, analyses), usually plausible on their face, ***to attempt to elicit a positive study result from a failed study – a practice sometimes referred to as data-dredging*** . . . . Although post hoc analyses of trials that fail on their prospectively specified endpoints might be useful for generating hypotheses for future testing, they do not yield definitive results. ***The results of such analyses can be biased because the choice of analyses can be influenced by a desire for success.***

131. The April 6, 2021 press release included the below chart, showing the analyses as originally reporting (*i.e.*, the manipulated data) and the results using the pre-specified analysis. FibroGen admitted that "based on these analyses ***we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen].***" As reflected below, the greatest manipulation involved the MACE endpoint for the incident dialysis patients, who presented a key market because Epogen was too unsafe for

that population. The manipulated data had been submitted with Roxadustat's NDA, so FibroGen stated it would "promptly . . . clarify this issue with the FDA."

	Analyses with post-hoc stratification factors	Analyses with pre-specified stratification factors
	HR (95% Confidence Interval)	**HR (95% Confidence Interval)**
Non Dialysis (OLYMPUS, ANDES, ALPS N=4,270); ITT		
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)
Dialysis Dependent (HIMALAYAS, SIERRAS, ROCKIES N=3,880); OT-7		
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)
Incident Dialysis (N=1,526); OT-7		
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)

132. Also on April 6, 2021, FibroGen held a "Business Update Call" in connection with the press release. During the call, the Individual Defendants confirmed that "the analysis with the prespecified stratification factors [had] not been previously publicly reported." They also revealed that the FDA had scheduled the AdCom meeting for July 15, 2021, suggesting that they only revealed the true data once the FDA had formally scheduled the AdCom review and they could no longer conceal the information.

133. On this news, the Company's stock price fell $15.83, or 45%, over the next two trading sessions to close at $18.81 per share on April 8, 2021.

134. Many analysts and nephrology experts concluded that the manipulation "could [not have] happen[ed] accidentally." An article by the American Society of Nephrology stated "the net effect" of the "statistical shenanigans" was "to remove [R]oxadustat's evident safety advantage compared with the drugs it would presumably replace." An article in pharmaceutical news outlet *Evaluate Vantage* stated "FibroGen's staggering admission" "stretches the bounds of credibility," and defendants would "struggle to shake suspicions" regarding their role in the "sorry debacle." Biotechnology publication, *STAT+*, stated: "the company has been touting false heart safety data [] for at least two years—a shocking revelation." *STAT+* described the conduct as the "worst case of data manipulation in years," stating that "FibroGen cheated." *STAT+* further asked, "how can anyone – investors, physicians, regulators – trust [a] company that spent nearly two years touting cardiovascular safety data that turns out to have been falsified?" The major pharmaceutical and biotechnology publication, *FiercePharma*, stated the "data doctoring" was a "stunning revelation":

> FibroGen admitted to presenting roxadustat data manipulated to make the anemia drug look safer than it is… [t]he fact that all nine analyses across the patient groups looked less favorable for [R]oxadustat after the change raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better.

135. However, the Individual Defendants continued to make materially misleading statements. During the April 6, 2021 conference call, defendant Conterno

contended that management "continue[s] to have confidence in Roxadustat's benefit-risk profile." Defendant Eisner also stated that "these analyses do not change the Company's assessment that Roxadustat is comparable to placebo in [NDD] patients and to [Epogen] in [DD] patients using MACE to measure cardiovascular safety."

136. During the same call, analysts specifically asked whether the pre-agreed reference point for non-inferiority was 1.25 or 1.3—a significant difference because the analyses using pre-specified factors showed that the upper bounds for the MACE and ACM endpoints for NDD patients exceeded 1.25 and could require a "black box" warning if that were the non-inferiority margin used by the FDA. Defendant Conterno responded that in NDD, "we basically show comparability relative to placebo. With regards to the 1 point to any measures of excess risk, you mentioned 1.25 or 1.3, I think I said in a number of different occasions that we do not have a pre-agreed non-inferiority margin with the FDA." He then reiterated the "critically important message" that "our conclusions . . . in NDD and DD that we're comparable to placebo in NDD and comparable to DD in EPO have not changed from a safety perspective."

137. On the April 6, 2021 call, Defendant Conterno also claimed that the data manipulation only "recently came to the attention of members of our senior management team, including myself, during our preparation for the upcoming"

AdCom. Prior management became the scapegoat, as defendant Conterno said the failure to detect the issue was the result of management turnover (*i.e.*, the death of Neff and the "retirement" of defendant Yu).

138. This was resoundingly rejected by analysts as "stretch[ing] the bounds of credibility" because these results had been repeated over the course of a year while the Individual Defendants prepared for a potential AdCom review and defendant Conterno himself had concluded the data was "extremely clean" based on his own review. A *FiercePharma* article published on April 7, 2021 doubted defendant Conterno's stance to "immediately distance[] senior management from the data doctoring" because it was implausible that the Individual Defendants were unaware of the data submitted in the "do-or-die FDA filing."

139. On May 10, 2021, FibroGen held a conference call in connection with its first quarter 2021 financial results, during which defendant Conterno reiterated that the data provided on April 6 "does not impact our overall conclusions regarding the comparability with respect to cardiovascular safety of Roxadustat to [Epogen] in [DD] patients and to placebo in [NDD] patients." He "reiterate[d] that we continue to have confidence in the Roxadustat data and in the safety and efficacy profile demonstrated in the Phase 3 program."

140. On May 13, 2021, at the Bank of America Annual Healthcare Conference, defendant Conterno reiterated that Roxadustat was "comparable on both

[DD] and [NDD] comparable to ESAs on [DD] onto placebo on [NDD]" and "can be an ideal choice there ***given the strength of our data***, in particular in incident dialysis."

141. On June 4, 2021, at the Jefferies Healthcare Conference, defendant Conterno highlighted that "Roxadustat has shown comparability when it comes to both placebo in [NDD] and relative to EPO in DD." He went on to claim that the hazard ratio for DD patients was "still below 1 and it looks very, very positive."

The Truth Fully Emerges

142. On July 15, 2021, a briefing document released in advance of the AdCom meeting revealed that the FDA had mandated critical, prespecified "sensitivity" analyses and that as a consequence, the true study results were even worse than FibroGen had reported on April 6, 2021. The Individual Defendants had claimed that the FDA had agreed to the ITT analysis as the primary prespecified analysis for NDD patients and the OT+7 ("on treatment plus 7 days") analysis as the primary prespecified analysis for DD and incident dialysis patients. In the briefing document, the FDA revealed that it had also required prespecified sensitivity analyses critical to evaluating the drug's safety in both populations. The prespecified sensitivity analyses showed that, for NDD patients, the MACE endpoint averaged 1.38, with a lower bound of 1.11 and an upper bound of ***1.70***, and that the ACM endpoint averaged 1.40, with a lower bound of 1.08 and an upper bound of ***1.82***.

Moreover, for DD patients, which results the Board failed to even review prior to submission of the NDA, the MACE endpoint averaged 1.14, with a lower bound of 1.00 and an upper bound of ***1.30***, and the ACM endpoint averaged 1.17, with a lower bound of 1.02 and an upper bound of ***1.35***. Therefore, the hazard ratios for all of the analyses were above the non-inferiority margin that the Individual Defendants claimed the FDA would use, *i.e.*, 1.3.

Non-Dialysis Dependent (NDD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	1.38 (1.11, **1.70**)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)	1.40 (1.08, **1.82**)

Dialysis Dependent (DD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)	1.14 (1.00, **1.30**)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)	1.17 (1.02, **1.35**)

143. Worse still, during the AdCom meeting, representatives from the FDA stated that FibroGen and "FDA did not agree prospectively on a [non-inferiority] risk margin." And, the FDA "do[es] not agree with [FibroGen's] proposed [non-inferiority] margin of 1.3, as it was defined after results of the study were known." In fact, the FDA indicated during pre-NDA meetings, approximately two years earlier, that it "had a goal of 1.25," noting also that "that's what we discussed during meetings[,] [s]o that's why ***there was not an agreement on 1.3***."

144. Overall, the AdCom concluded that Roxadustat's "benefits are difficult to calculate here" and that the drug posed numerous safety risks. For example, the briefing document noted that "[t]he rate of death was higher in patients who had received [R]oxadustat" compared to those who received Epogen. Due to the safety and efficacy concerns, the panel voted 13-1 against approval of Roxadustat in NDD patients and voted 12-2 against approval of Roxadustat in DD patients.

145. On this news, the Company's stock price fell $10.59, or 42%, to close at $14.35 per share on July 16, 2021.

146. On August 11, 2021, FibroGen announced what the market was already expecting – receipt of a Complete Response Letter from the FDA confirming that the Roxadustat NDA would not be approved for any patient population.

147. On February 28, 2022, FibroGen disclosed in its annual report on Form 10-K that: "In the fourth quarter of 2021, FibroGen received a subpoena from the SEC requesting documents related to roxadustat's pooled cardiovascular safety data. We have been fully cooperating with the SEC's investigation." The SEC investigation is ongoing.

Reasons Why the Statements Were Misleading

148. The foregoing public statements were misleading because defendants had improperly manipulated the Roxadustat safety data post hoc in order to make the drug appear better and safer than it was. As later revealed, under the properly

used prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was more dangerous than placebo and inferior to and caused more deaths than Epogen. Further, under the FDA's prespecified analyses, there was no statistically significant "superiority" of Roxadustat over Epogen for the MACE+ endpoint in the incident dialysis population, nor was there "a trend toward reduced [MACE] risk for patients on Roxadustat." Based on the actual prespecified FDA analyses, Defendants admitted in the April 6, 2021 press release that they "[could not] conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE and MACE+ in incident dialysis compared to [Epogen]. Similarly, there were no "statistically significant improvements" in quality-of-life measures for NDD patients taking Roxadustat.

149. Under the FDA's prespecified sensitivity analyses which had not been publicly disclosed, Roxadustat was actually more dangerous than placebo and decidedly inferior to and causing more deaths than Epogen, rendering Roxadustat too dangerous to be approved at all, for any patient population. Defendants' statement that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, their own undisclosed analyses showed that Roxadustat was less safe than Epogen, which already had the "Black Box" warning. Moreover, the Board was specifically told

the FDA believed a "Black Box" warning would be necessary at a time when the Company's public disclosures were claiming that one would not be.

Roxadustat Continues to Fail, Putting FibroGen's Partnership with AstraZeneca at Risk

150. In the months following the FDA's high-profile rejection of Roxadustat, FibroGen and AstraZeneca engaged in "significant discussions" about what to do with the drug after the FDA refused to approve it. By June 2022, however, FibroGen's CEO, Defendant Conterno, announced that the Company and AstraZeneca had "not been able to find a path forward for AstraZeneca to fund further Roxadustat development of anemia of CKD in the U.S."

151. Accordingly, the Company announced that it did "not expect to receive most or all of the remaining" milestones under its collaboration agreement with AstraZeneca.[7] Moreover, because AstraZeneca holds exclusive rights for the development and commercialization of Roxadustat in the United States, Defendant Conterno announced that there was no way for the Company to proceed without AstraZeneca.

152. Analysts discussed the possibility that AstraZeneca would not be willing to fund another large phase 3 trial at all, particularly as a rival drug got closer

[7] FibroGen, Inc., Quarterly Report (Form 10-Q) (May 9, 2022).

to approval.[8]

153. Nevertheless, Defendant Conterno assured the market that AstraZeneca was still involved in Roxadustat's development as a treatment for anemia in myelodysplastic syndromes ("MDS"), and that top-line phase 3 data for that program was expected in the first half of 2023.

154. On May 5, 2023, however, the Company announced that the Phase 3 Matterhorn trial for Roxadustat in patients with anemia associated with MDS had missed its primary efficacy endpoint.

155. Days later, in its quarterly report filed on Form 10-Q with the SEC ("2Q 2023 10-Q"), FibroGen conceded it was "not [] able to agree on a path forward for AstraZeneca to fund further roxadustat development for CKD anemia in the U.S." and that the Company therefore did "not expect to receive most or all of" the additional potential milestone payments—totaling more than $800 million—under the collaboration agreement with AstraZeneca.

156. Although FibroGen and AstraZeneca have been collaborating on Roxadustat since 2013, the collaboration agreement gives AstraZeneca the right to terminate the partnership upon negative clinical results and other developmental,

[8] In February 2023, GSK's oral anemia drug, branded as Jesduvroq, won a class-first approval to treat patients with anemia caused by CKD who had been on dialysis for at least four months.

regulatory, or commercialization setbacks. Indeed, the Company disclosed in its 2Q 2023 10-Q that "[t]here is a significant risk that our U.S./Rest of World Collaboration Agreement with AstraZeneca will be amended or terminated."

157. Roxadustat remains unapproved by the FDA for used in the United States.

Defendants Yu, Schoeneck, Kurkijärvi, Kearns, Cotroneo, and Chung Sold More Than $19 Million in FibroGen Stock While in Possession of Material Non-Public Information

Defendant Yu

158. Defendant Yu was the Company's CMO with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

159. As set forth herein, defendant Yu possessed material negative information which she knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Yu consciously acted to exploit her knowledge by selling nearly $1.9 million in FibroGen stock to her substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
Mar. 14, 2019	9,145	$56.30	$514,864
June 14, 2019	3,420	$40.96	$140,083
Sept. 16, 2019	3,419	$40.92	$139,405
Dec. 16, 2019	3,420	$46.68	$159,646
July 25, 2020	3,351	$42.35	$141,915
Sept. 3, 2020	10,000	$50.89	$508,900
Sept. 16, 2020	3,351	$44.01	$147,478
Dec. 16, 2020	3,350	$44.61	$139,394

		TOTAL PROCEEDS:	**$1,891,685**

160. Defendant Yu thus used her fiduciary position to enrich herself and failed to discharge her duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved. She also took affirmative steps to destroy evidence on her laptop related to this litigation.

Defendant Schoeneck

161. Defendant Schoeneck was the Company's Interim CEO and a director with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

162. As set forth herein, defendant Schoeneck possessed material negative information which he knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Schoeneck consciously acted to exploit his knowledge by selling over $500,000 in FibroGen stock to his substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
Jan. 7, 2019	2,000	$45.90	$91,800
Feb. 7, 2019	2,000	$57.17	$114,340
Mar. 7, 2019	1,620	$54.62	$88,484
Mar. 7, 2019	380	$55.23	$20,987
Apr. 8, 2019	1,500	$46.80	$105,800
May 7, 2019	1,500	$46.80	$70,200
May 7, 2019	500	$47.69	$23,845

		TOTAL PROCEEDS:	**$515,456**

163. Defendant Schoeneck thus used his fiduciary position to enrich himself and failed to discharge his duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved.

Defendant Kurkijärvi

164. Defendant Kurkijärvi was a director and a member of the Audit Committee of the Company with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

165. As set forth herein, Defendant Kurkijärvi possessed material negative information which he knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Kurkijärvi consciously acted to exploit his knowledge by selling nearly $4 million in FibroGen stock to his substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
Apr. 8, 2019	3,427	$52.95	$181,460
Apr. 8, 2019	573	$53.51	$30,661
Apr. 15, 2019	4,000	$48.09	$192,360
May 8, 2019	5,056	$45.83	$231,716
May 8, 2019	944	$46.51	$43,905
June 6, 2019	2,942	$37.20	$109,442
June 6, 2019	3,058	$38.49	$117,702
July 8, 2019	4,600	$42.35	$194,810
July 8, 2019	1,400	$43.40	$60,760

Aug. 5, 2019	6,000	$45.22	$271,320
Sep. 9, 2019	5,580	$40.90	$228,222
Sep. 9, 2019	420	$41.67	$17,501
Oct. 7, 2019	6,000	$36.73	$220,380
Nov. 7, 2019	4,514	$38.08	$171,893
Nov. 7, 2019	1,486	$38.85	$57,731
Dec. 9, 2019	6,000	$47.50	$285,000
Jan. 6, 2020	6,000	$42.66	$255,960
Feb. 10, 2020	6,000	$42.69	$256,140
Dec. 28, 2020	5,901	$40.39	$238,341
Dec. 28, 2020	100	$41.14	$4,114
Jan. 14, 2021	5,999	$40.04	$240,200
Jan. 19, 2021	6,000	$43.38	$260,280
Feb. 17, 2021	5,156	$52.31	$269,710
Feb. 17, 2021	844	$52.93	$44,673
		TOTAL PROCEEDS:	**$3,984,284**

166. Defendant Kurkijärvi thus used his fiduciary position to enrich himself and failed to discharge his duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved.

Defendant Kearns

167. Defendant Kearns was a director of the Company with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

168. As set forth herein, defendant Kearns possessed material negative information which he knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Kearns consciously acted to

exploit his knowledge by selling more than $1 million in FibroGen stock to his substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
Mar. 19, 2020	18,000	$23.17	$417,060
Mar. 11, 2021	18,000	$35.02	$630,360
		TOTAL PROCEEDS:	**$1,047,420**

169. Defendant Kearns thus used his fiduciary position to enrich himself and failed to discharge his duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved.

Defendant Cotroneo

170. Defendant Cotroneo was the Company's CFO with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

171. As set forth herein, defendant Cotroneo possessed material negative information which he knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Cotroneo consciously acted to exploit his knowledge by selling nearly $7 million in FibroGen stock to his substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
Feb. 28, 2019	14,787	$60.07	$888,255
Mar. 19, 2019	7,665	$55.41	$424,717
June 18, 2019	3,201	$43.12	$138,027
Sep. 17, 2019	3,201	$41.38	$132,457
Dec. 20, 2019	46,727	$45.51	$2,126,545
Dec. 20, 2019	12,729	$46.27	$588,970

Mar. 16, 2020	9,239	$26.36	$243,540
June 16, 2020	3,928	$39.68	$155,863
Aug. 7, 2020	22,554	$48	$1,082,592
Sep. 3, 2020	15,004	$50.91	$763,853
Sep. 15, 2020	3,070	$43.63	$133,944
Dec. 15, 2020	3,068	$43.60	$133,764
June 15, 2021	4,053	$25.62	$103,837
		TOTAL PROCEEDS:	**$6,916,369**

172. Defendant Cotroneo thus used his fiduciary position to enrich himself and failed to discharge his duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved.

Defendant Chung

173. Defendant Chung was the Company's Senior Vice President of China Operations with a highly sophisticated understanding of the Company's Phase 3 study results and their import.

174. Defendant Chung possessed material negative information which she knew was being concealed from investors, including the data manipulation of Roxadustat Phase 3 results. Defendant Chung consciously acted to exploit her knowledge by selling over $1 million in FibroGen stock to her substantial benefit, as follows:

Date	**Shares Sold**	**Price**	**Proceeds**
May 7, 2019	1,925	$46.04	$88,627
May 7, 2019	3,500	$46.70	$163,450

May 7, 2019	200	$47.44	$9,488
May 8, 2019	4,125	$46.20	$190,575
May 8, 2019	1,500	$46.62	$69,930
June 18, 2019	5,625	$44.08	$247,950
June 19, 2019	5,625	$44.02	$247,612
July 10, 2019	5,025	$44.75	$224,868
July 10, 2019	600	$45.14	$27,084
July 11, 2019	5,525	$45.13	$249,343
July 11, 2019	100	$45.72	$4,572
Aug. 22, 2019	5,325	$43.79	$233,181
Aug. 22, 2019	300	$44.67	$13,401
Aug. 23, 2019	3,225	$42.05	$135,611
Aug. 23, 2019	1,816	$42.94	$77,979
Aug. 23, 2019	584	$43.68	$25,509
Sep. 19, 2019	2,225	$40	$89,000
Sep. 19, 2019	3,400	$40.75	$138,550
Sep. 20, 2019	5,625	$39.87	$224,268
Oct. 8, 2019	3,225	$36.55	$117,873
Oct. 8, 2019	2,400	$37.10	$89,040
Oct. 9, 2019	5,625	$36.58	$205,762
Nov. 13, 2019	5,625	$34.54	$194,287
Nov. 14, 2019	3,600	$34.50	$124,200
Nov. 14, 2019	2,025	$35.18	$71,239
Dec. 16, 2019	2,850	$46.80	$133,380
Dec. 16, 2019	2,775	$47.37	$131,451
Dec. 17, 2019	5,336	$46.95	$250,525
Dec. 17, 2019	289	$47.47	$13,718
Jan. 6, 2020	5,625	$42.98	$241,762
Jan. 7, 2020	5,625	$42.76	$240,525
Feb. 11, 2020	5,625	$44.48	$250,200
Feb. 12, 2020	5,025	$45.94	$230,848
Feb. 12, 2020	600	$46.28	$27,768
Mar. 18, 2020	905	$23.69	$21,439
Mar. 18, 2020	1,500	$24.56	$36,840
Mar. 18, 2020	1,500	$25.68	$38,520
Mar. 19, 2020	300	$23.93	$7,179
Mar. 19, 2020	830	$25.32	$21,015
Mar. 19, 2020	6,215	$26.08	$162,087

		TOTAL PROCEEDS:	**$5,070,665**

175. Defendant Chung thus used her fiduciary position to enrich herself and failed to discharge her duties by causing the Company to candidly reveal the truth of the Phase 3 results and the resulting risk that the NDA would not be approved.

The False and Misleading Proxy Statements

176. In addition to the above false and misleading statements issued and/or caused to be issued by the Individual Defendants, the Individual Defendants caused the Company to issue false and misleading proxy statements on April 23, 2020 (the "2020 Proxy") and April 13, 2021 (the "2021 Proxy").[9] The 2020 Proxy and the 2021 Proxy are collectively referred to herein as the "Proxies."

177. The 2020 Proxy recommended, among other things, that shareholders elect Individual Defendants Conterno, Kearns, Kurkijärvi, and Lema as directors for three-year terms. The 2020 Proxy assured stockholders that the Board and its committees regularly assessed and managed the risks that FibroGen faces, including

[9] These proxy allegations are based solely on negligence, they are not based on any allegations of recklessness or knowing conduct by or on behalf of the Individual Defendants, and they did not allege fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to the proxy allegations and related claims.

legal and regulatory risks, financial controls, and risks associated with compensation programs and plans. Specifically, the 2020 Proxy stated:

> **ROLE OF THE BOARD IN RISK OVERSIGHT**
>
> One of the Board's key functions is informed oversight of the Company's risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of the Board that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the Company. Our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors legal matters and compliance with legal and regulatory requirements regarding the Company's financial statements and accounting or other policies. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs have the potential to encourage excessive risk-taking. It is the responsibility of the committee Chairs to report findings regarding material risk exposures to our board of directors as quickly as possible. In addition, our board of directors meets with certain members of our executive team, including the heads of our business, compliance and regulatory functions, who discuss the risks and exposures involved in their respective areas of responsibility, as well as any developments that could impact our risk profile or other aspects of our business.

178. The 2020 Proxy also noted that one of the functions of the Audit Committee was to review the Company's policies on risk assessment and risk

management.

179. Further, the 2020 Proxy touted purportedly key operational results regarding the development of Roxadustat, highlighted the achievements of named executive officers relating to the development of Roxadustat, and assured investors that Defendant Conterno "is exceptionally qualified to serve as our Chief Executive Office[r] and on our board of directors as we prepare for the global commercialization of Roxadustat and continue the advancement of our clinical programs."

180. In describing the Company's 2019 Bonus Plan, the 2020 Proxy claimed that all of the 2019 corporate goals concerning Roxadustat had been achieved to at least a 50% achievement level. Indeed, three executive officers (including Defendants Chung and Yu) received an additional special RSU award for, *inter alia*, completing roxadustat Phase 3 studies in the U.S. and Europe.

181. The 2020 Proxy assured stockholders that the Individual Defendants were involved with FibroGen's operations, actively monitored the Company's risks and exposures, and had achieved significant goals relating to the development and commercialization of roxadustat. In reality, the Individual Defendants were utterly failing in their oversight duties by allowing the Company to operate with inadequate internal controls, which resulted in the manipulation of data to make FDA approval of Roxadustat appear more likely and the issuance by the Company of various false

and misleading statements, including that roxadustat had met certain objectives it had not actually met.

182. The 2021 Proxy contained comparable provisions to the 2020 Proxy regarding risk oversight and the Audit Committee's role in risk assessment and risk management. Moreover, although the 2021 Proxy noted that the Company had not received FDA approval for its NDA for Roxadustat, Individual Defendants nevertheless touted the substantial work the Company had done towards reaching that goal and highlighted other purported achievements related to the drug. As such, the 2021 Proxy was also materially false and misleading.

183. The 2021 Proxy recommended, among other things, that shareholders elect Individual Defendants Schoeneck, Henderson, and Ho as directors for three-year terms.

184. As a result of the materially false and misleading statements in the Proxies, the Company's stockholders voted via uninformed stockholder votes to reelect the Individual Defendants proposed for reelection in the Proxies.

THE INDIVIDUAL DEFENDANTS' BREACHES OF DUTIES

185. By reason of their positions as officers, directors, and/or fiduciaries of FibroGen and because of their ability to control the business and corporate affairs of FibroGen, at all relevant times, the Individual Defendants owed FibroGen and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were

required to use their utmost ability to control and manage FibroGen in a fair, just, honest, and equitable manner. The Individual Defendants were required to act in furtherance of the best interests of FibroGen and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to FibroGen and its shareholders a fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

186. The Individual Defendants, because of their positions of control and authority as directors and/or officers of FibroGen, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with FibroGen, each of the Individual Defendants had knowledge of material non-public information regarding the Company.

187. To discharge their duties, the officers and directors of FibroGen were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of FibroGen were required to, among other things:

(a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

(b) Exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority;

(c) Exercise good faith to ensure that the Company's communications with the public and with shareholders are made with due candor in a timely and complete fashion; and

(d) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

Duties Pursuant to the Company's Code of Business Conduct

188. The Individual Defendants, as officers and/or directors of FibroGen, were bound by the Company's Code of Business Conduct and Ethics[10] (the "Code of Conduct") which required the following:

> We expect every employee, officer and director to read and understand this Code and its application to the performance of his or her business responsibilities. References in this Code to employees are intended to cover officers and, as applicable, directors.
>
> Officers, managers and other supervisors are expected to develop in employees a sense of commitment to the spirit, as well as the letter, of this Code. Supervisors are also expected to ensure that all agents and contractors conform to Code standards when working for or on behalf of the Company. Nothing in this Code alters your employment relationship with the Company.
>
> ***
>
> **1. HONEST AND ETHICAL CONDUCT**

[10] *See* FibroGen, Inc. Code of Business Conduct and Ethics (Sept. 2017), https://fibrogen.gcs-web.com/static-files/a9d04c12-9fb7-41b7-b5e9-19d8eeb73361.

It is the policy of the Company to promote high standards of integrity by **conducting our affairs in an honest and ethical manner**. The integrity and reputation of the Company depends on the honesty, fairness and integrity brought to the job by each person associated with us. Unyielding personal integrity is the foundation of corporate integrity.

2. LEGAL COMPLIANCE

Obeying the law is the foundation of this Code. Our success depends upon each employee, officer and director operating within legal guidelines and cooperating with local, national and international authorities. We expect employees, officers and directors to understand the legal and regulatory requirements applicable to their business units and areas of responsibility. While we do not expect you to memorize every detail of these laws, rules and regulations, we want you to be able to determine when to seek advice from others. If you do have a question in the area of legal compliance, it is important that you not hesitate to seek answers from your supervisor or the Compliance Officer.

Disregard of the law will not be tolerated. Violation of laws, rules and regulations of any country may subject an individual, as well as the Company, to civil and/or criminal penalties. You should be aware that conduct and records, including email, are subject to internal and external audits and to discovery by third parties in the event of a government investigation or civil litigation. It is in everyone's best interests to know and comply with our legal obligations.

3. INSIDER TRADING

Employees, officers and directors who have access to confidential information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about the Company or about companies with which we do business is considered confidential (or "***inside***") information. **To use material nonpublic information in connection with buying or selling securities, including "tipping" others who might make an investment decision on the basis of this information, is not only unethical, it is illegal. Employees, officers**

and directors must exercise the utmost care when handling material inside information.

We have adopted a separate Insider Trading and Trading Window Policy with which you will be expected to comply as a condition of your employment with the Company. You should consult our Insider Trading and Trading Window Policy for more specific information on the definition of "inside" information and on buying and selling our securities or securities of companies with which we do business.

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5. RESEARCH AND DEVELOPMENT; REGULATORY COMPLIANCE

The research and development of biopharmaceutical products is subject to a number of legal and regulatory requirements, including **standards related to ethical research procedures and proper scientific conduct. We expect our employees, officers, and directors to comply with all such requirements.**

***

9. CONFLICTS OF INTEREST

We respect the rights of our employees, officers, and directors to manage their personal affairs and investments and do not wish to impinge on their personal lives. However, employees, officers and directors should avoid conflicts of interest that occur when their personal interests may interfere in any way with the performance of their duties or the best interests of the Company. **A conflicting personal interest could result from an expectation of personal gain now or in the future or from a need to satisfy a prior or concurrent personal obligation.** We expect our employees to be free from influences that conflict with the best interests of the Company or might deprive the Company of their undivided loyalty in business dealings. Even the appearance of a conflict of interest where none actually exists can be damaging and should be avoided. Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest are prohibited unless specifically authorized as described below.

***

Although no list can include every possible situation in which a conflict of interest could arise, the following are examples of situations that may, depending on the facts and circumstances, involve problematic conflicts of interests for employees, officers and directors:

***

- **Taking personal advantage of corporate opportunities.** See Section 10 for further discussion of the issues involved in this type of conflict.

***

10. CORPORATE OPPORTUNITIES

You may not take personal advantage of opportunities for the Company that are presented to you or discovered by you as a result of your position with us or through your use of corporate property or information, unless authorized by your supervisor, the Compliance Officer or, if you are an executive officer or director, the Audit Committee, as described in Section 9. Even opportunities that are acquired privately by you may be questionable if they are related to our existing or proposed lines of business. Significant participation in an investment or outside business opportunity that is directly related to our lines of business must be pre-approved. **You may not use your position with us or corporate property or information for improper personal gain**, nor should you compete with us in any way. If you discover or are presented with a business opportunity through the use of corporate property or information or because of your position with the Company, you should first present the business opportunity to the Company.

11. MAINTENANCE OF CORPORATE BOOKS, RECORDS, DOCUMENTS AND ACCOUNTS; FINANCIAL INTEGRITY; PUBLIC REPORTING

The integrity of our records and public disclosure depends upon

the validity, accuracy and completeness of the information supporting the entries in our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries, whether they relate to financial results or otherwise, is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, partners, contributors, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:

- **No entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities or misclassifies any transactions as to accounts or accounting periods**;
- **Transactions be supported by appropriate documentation**;
- **The terms of commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records**;
- **Employees comply with our system of internal controls**; and
- No cash or other assets be maintained for any purpose in any unrecorded or "off-the-books" fund.

(Emphasis in bold and underline added).

189. The Individual Defendants failed to adhere to the Code of Conduct by allowing the Company to issue materially false and misleading statements regarding Roxadustat's clinical trial data and claiming that the drug had met certain objectives, which would likely lead to FDA approval. Further, they allowed or failed to prohibit

insider trading at the Company.

190. In addition to these duties, the Audit Committee Defendants, who served on the Audit Committee during the Relevant Period – Edwards, Ho, Kurkijärvi, Lema, Riggs, and Schoeneck – owed specific duties to FibroGen under the Charter of the Audit Committee of the Board of Directors (the "Audit Charter").[11] Specifically, the Audit Charter provided for, *inter alia*, the following responsibilities of the Audit Committee Defendants:

> **PURPOSE AND POLICY**
>
> The primary purpose of the Audit Committee (the "***Committee***") of the Board of Directors (the "***Board***") of FibroGen, Inc. (the "***Company***") shall be to act on behalf of the Board in fulfilling the Board's oversight responsibilities with respect to (i) the Company's corporate accounting and financial reporting processes, systems of internal control over financial reporting and audits of financial statements, systems of disclosure controls and procedures, as well as the quality and integrity of the Company's financial statements and reports, … (ii
> (iii) the review of any reports or other disclosure required by the applicable rules and regulations of the Securities and Exchange Commission (the "***SEC***") to be included in the Company's annual proxy statement, periodic reports, and registration statements within the scope of authority outlined herein, (iv) the review of and approval or disapproval of any related party transactions, (v) the review of any complaints or violations regarding accounting, internal accounting controls or auditing matters, the Company's Code of Conduct and Ethics, or any anti-bribery or anti-corruption policy, and the supervision of any related investigation and implementation of any

[11] *See* FibroGen, Inc. Charter of the Audit Committee of the Board of Directors (June 4, 2020), https://fibrogen.gcs-web.com/static-files/8d232fec-1ae0-4460-bd9c-efe8a8c8e8b8.

corrective actions, and (vi) the performance of the Company's internal audit function, if any.

The policy of the Committee, in discharging these obligations, shall be to maintain and foster an open avenue of communication between the Committee and the Auditors and the Company's financial management and internal audit teams.

***

OPERATING PRINCIPLES AND PROCESSES

In fulfilling its functions and responsibilities, the Committee should give due consideration to the following operating principles and processes:

- *Communication* – Regular and meaningful contact with the Board, members of senior management and independent professional advisors to the Board and its various committees, as applicable, shall be encouraged as a means of strengthening the Committee's knowledge of relevant current and prospective corporate accounting and financial reporting issues.

***

RESPONSIBILITIES

The Committee's responsibility is one of oversight. The members of the Audit Committee are not employees of the Company, and they do not perform, or represent that they perform, the functions of management or the Auditors.

***

The Committee shall **oversee the Company's financial reporting process on behalf of the Board,** shall have direct responsibility for the appointment, compensation, retention and oversight of the work of the Auditors and any other registered public accounting firm engaged for the purpose of performing other review or attest services for the Company. … To implement the Committee's purpose and policy, the Committee shall be charged

with the following functions and responsibilities with the understanding, however, that the Committee may supplement or (except as otherwise required by applicable laws or requirements of any stock exchange on which any of the Company's capital stock may be listed) deviate from these activities as appropriate under the circumstances:

***

8. ***Audited Financial Statement Review.*** To review, upon completion of the audit, the financial statements proposed to be included in the Company's Annual Report on Form 10-K to be filed with the SEC and any disclosure from the Company's CEO and CFO to be made in connection with the certification thereof, and to recommend whether or not such financial statements should be so included.

9. ***Annual Audit Results.*** To review with management and the Auditors, the results of the annual audit, including the Auditors' assessment of the quality of the Company's accounting principles and practices, the Auditors' views about qualitative aspects of the Company's significant accounting practices, the reasonableness of significant judgments and estimates (including material changes in estimates and analyses of the effects of alternative GAAP methods on the financial statements), **all material findings, including misstatements and weaknesses, if any, [of] the adequacy of the disclosures in the financial statements,** and any other matters required to be communicated to the Committee by the Auditors under the standards of the PCAOB. **To review with management and inquire of the CEO, CFO, controller, Director of Internal Audit or any other persons requested by the Committee, regarding the subjective and objective quality and integrity of the Company's financial statements and earnings.**

***

11. ***Quarterly Results and Reports on Form 10-Q.*** To review with management and the Auditors, as appropriate, **the results of the Auditors' review of the Company's quarterly financial statements and any disclosure from the Company's CEO and CFO to be made in connection with the certification of the**

Company's quarterly reports filed with the SEC, prior to public disclosure of quarterly financial information, if practicable, or filing with the SEC of the Company's Quarterly Report on Form 10-Q and any other matters required to be communicated to the Committee by the Auditors under the standards of the PCAOB. To review with management and the Auditors, to the extent appropriate, other relevant reports or financial information submitted by the Company to any governmental body or the public, including management certifications as required in Item 601(b)(31) of Regulation S-K and relevant reports rendered by the Auditors (or summaries thereof).

12. ***Management's Discussion and Analysis.*** To review with management and the Auditors, as appropriate, the Company's disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" in its periodic reports and other filing with the SEC.

13. ***Press Releases.*** To review with management and the Auditors, to the extent appropriate, **earnings press releases, as well as the substance of financial information and earnings guidance provided to analysts and ratings agencies** (including, without limitation, reviewing any pro forma or non-GAAP information), which discussions may be general discussions of the type of information to be disclosed or the type of presentation to be made. The Chair of the Committee may represent the entire Committee for purposes of this discussion.

14. ***Accounting Principles and Policies.*** To review with management and the Auditors, as appropriate, significant issues that arise regarding accounting principles and financial statement presentation, including critical accounting policies and practices, alternative accounting policies available under GAAP related to material items discussed with management, the potential impact on the Company's financial statements of off-balance sheet structures **and any other significant reporting issues and judgments, significant regulatory, legal and accounting initiatives or developments that may have a material impact on the Company's financial statements, compliance programs and policies** if, in the judgment of the Committee, such review is necessary or appropriate.

15. ***Risk Assessment and Management.*** To review and discuss with management and the Auditors, as appropriate, **the Company's guidelines and policies with respect to financial risk management and financial risk assessment, including the Company's major financial risk exposures and the steps taken by management to monitor and control these exposures.**

***

21. ***Internal Control over Financial Reporting; Disclosure Controls.*** To confer with management, the Director of Internal Audit, if any, and the Auditors, as appropriate, **regarding the scope, adequacy, and effectiveness of internal control over financial reporting, including computerized information system controls and security, and the Company's disclosure controls and procedures, including any significant deficiencies and significant changes in internal controls. To obtain reports on significant findings and recommendations with respect to internal controls over financial reporting, together with management responses and any special audit steps adopted in light of any material control deficiencies.**

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26. ***Ethical Compliance.*** To review with management, including the Company's general counsel and Director of Internal Audit, if any, the results of management's efforts to monitor compliance with the Company's programs and **policies designed to ensure adherence to applicable laws and rules, as well as to its Code of Business Conduct and Ethics, including review and oversight of related-party transactions as required by applicable laws or requirements of any stock exchange on which any of the Company's capital stock is listed.**

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32. ***Proxy Report.*** To oversee the preparation of the report required by the rules of the SEC to be included in the Company's annual proxy statement.

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> **34.** ***Report to Board.*** To report to the Board with respect to **material issues that arise regarding the quality or integrity of the Company's financial statements, the Company's compliance with legal or regulatory requirements,** the performance or independence of the Auditors, the performance of the Company's internal audit function (as applicable) or such other matters as the Committee deems appropriate from time to time or whenever it shall be called upon to do so.

***

> **37.** ***Other Legal and Finance Matters.*** To review, with the Company's counsel, **legal compliance and legal matters that could have a significant impact on the Company's financial statements.** To review, with management, the Company's finance function, including its budget, organization and quality of personnel.

(Emphasis in bold and underline added).

191. The Audit Committee Defendants failed to adhere to the Audit Charter and the Code of Conduct by issuing false and materially misleading public statements and filings with the SEC related to the Roxadustat's clinical trial data, falsely claiming that the drug had met certain objectives, and would likely receive FDA approval.

DAMAGES TO THE COMPANY

192. As a direct and proximate result of the Individual Defendants' conduct, FibroGen has been seriously harmed and will continue to be. Such harm includes, but is not limited to:

(a) Harm to the Company from the improper and deceptive use of post-hac analyses in the Roxadustat NDA submission;

(b) Costs incurred from incentive compensation, severance and related benefits paid to Yu, and from incentive compensation paid to Kurkijärvi;

(c) Defendants' ill-gotten gains from their insider trading;

(d) Legal fees paid in connection with the Securities Class Action and the SEC investigation; and

(e) Any funds paid to settle the Securities Class Action and resolve the SEC investigation or an eventual enforcement action.

193. In addition, FibroGen's business, goodwill, and reputation with its business partners, regulators, and shareholders has been gravely impaired. The Company still has not fully admitted the nature of its false statements and the true condition of its business. The credibility and motives of management are now in serious doubt.

194. The actions complained of herein have irreparably damaged FibroGen's corporate image and goodwill. For at least the foreseeable future, FibroGen will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and misled the investing public, such that FibroGen's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

195. Plaintiff brings this action derivatively in the right and for the benefit of FibroGen to redress injuries suffered, and to be suffered, by FibroGen as a direct result of the wrongdoing alleged herein. FibroGen is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

196. Plaintiff will adequately and fairly represent the interests of FibroGen in enforcing and prosecuting its rights.

197. Plaintiff has continuously been a shareholder of FibroGen at times relevant to the wrongdoing complained of and is a current FibroGen shareholder.

198. When this action was filed, FibroGen's Board of Directors consisted of eleven directors, including defendants Conterno, Schoeneck, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Lema, and Riggs. Plaintiff did not make a demand on the Board to institute this action because such a demand would be a futile, wasteful, and useless act, as set forth below.

The Roxadustat NDA Was Critical For The Company's Future Operations

199. At all relevant times, substantially all of FibroGen's revenue was derived from collaboration agreements for the development and commercialization of Roxadustat. For fiscal 2019, 83% of the Company's revenue was recognized from reaching various regulatory milestones for Roxadustat, including $50 million for the

submission of the NDA and $130.0 million for the submission of a regulatory application with European authorities. In fiscal 2020, all of the Company's revenue was related to Roxadustat. The total market for Roxadustat was expected to be approximately $3.5 billion, and many analysts estimated that approximately 90% of FibroGen's value was related to Roxadustat.

200. Thus, the regulatory approval of Roxadustat was "mission critical" at all relevant times, and the Board knew or should have known of key developments, including the analysis of safety data from Phase 3 trials and the accuracy of the data submitted to the FDA in connection with the NDA. At all relevant times, the Board had three committees: Audit, Compensation, and Nominating & Corporate Governance. None were specifically charged with oversight of the Company's data integrity, including adherence to protocols authorized by the FDA.

201. In addition to clinical trial data integrity being mission critical simply due to the fact that the Company's entire future outlook depended on the commercialization of drugs approved by the FDA, the Board was presented with several red flags alerting it that there could be problems with the Roxadustat safety data it was reviewing, and was being publicly reported to investors and submitted to the FDA. Two short reports specifically questioned whether the data was truthful and whether it had been produced pursuant to the prespecified analyses agreed to by the FDA. The Citizen's Petition similarly raised the same issue. The mysterious

"retirement" of Yu, shortly after the Citizen's Petition put an exclamation point on the issue, but the Board conducted no oversight of the issue. When the FDA sought additional analyses in December 2020, the Board still took no action.

202. The Board was specifically on notice that the FDA required certain "sensitivity analysis" to evaluate the Roxadustat NDA. During a September 5, 2019 Board meeting, defendants Conterno, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs reviewed and discussed that FibroGen had had "a successful pre-NDA meeting with the FDA with an agreement on pooling strategy and ***analysis methods for non-dialysis and dialysis.***" FGEN_220_0000113. One such "analysis method[]" was a "sensitivity analysis" measured on treatment plus 28 days. FGEN_220_0000120. However, the Board failed to even review the complete sensitivity results prior to submission of the NDA.

203. As was later revealed, the FDA told FibroGen ***during pre-NDA*** meetings which occurred prior to December 2019, that the FDA's goal was a hazard ratio below 1.25. The Board knew that the FDA had not agreed with the Company's proposal to use 1.3 as the hazard ratio end point. However, the Board failed to inquire into and was not informed regarding the FDA's position on the hazard ratio prior to submission of the NDA, even though the FDA's hazard ratio goal was one of the most important factors affecting the chances of approval of the NDA.

204. The Individual Defendants did not disclose these sensitivity results to stockholders, and it was not revealed until the ***FDA*** issued its briefing materials for the AdCom meeting in July 2021, nearly a year and a half after the Phase 3 safety results were first reported to the investing public.

205. Finally, as alleged herein, the books and records produced to Plaintiff contain no evidence whatsoever that the Board had in place ***any*** process for oversight of clinical trial data integrity. The Board conducted no oversight and was not informed of any management oversight to confirm the integrity of the study results submitted to the FDA. The Board delegated responsibility for such oversight to no committee. At no time from mid-2019 through April 2021, did the Board conduct any oversight over the Company's processes for clinical data management, programming, analysis or reporting, and Plaintiff infers that no formal processes existed for overseeing data management and integrity.

206. Further raising a reason to doubt that the Board acted in good faith is that the Board, while overseeing the Company's disclosures regarding Roxadustat, the Phase 3 results, and the NDA, permitted the Company to pervasively misrepresent communications with the FDA and the results themselves.

207. First, the Individual Defendants caused FibroGen to misleadingly represent that it had reached an agreement with the FDA to use a non-inferiority margin of 1.3, when in fact there was no such agreement. As was later revealed, the

FDA conveyed its goal of 1.25 to the Company at some point prior to December 2019. During the September 5, 2019 meeting, defendants Conterno, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs also discussed the significance of the safety data, indicating that Roxadustat exhibited "noninferiority to placebo" among NDD patients "***if*** usual & customary NI [non-inferiority] margin 1.3 applies." FGEN_220_0000120. While these directors discussed the "agreement [with the FDA] on pooling strategy and analysis methods," this language that Roxadustat was non-superior "***if*** . . . margin 1.3 applies" makes clear that there was no agreement with the FDA on this issue. *See* FGEN_220_0000113, FGEN_220_0000120. Indeed, the ***FDA*** revealed on July 15, 2021 that the agency "had a goal of 1.25" and "there was not an agreement on 1.3" as the non-inferiority margin.

208. Yet when the Individual Defendants announced the hazard ratios on November 8, 2019, they caused FibroGen to misleadingly suggest that the ITT analysis was "agreed upon with the FDA" using "a reference non-inferiority margin of 1.3." It was not until April 8, 2021, when the Company disclosed that manipulated data had been submitted to the FDA, did management begin to walk back these statements, claiming that FibroGen "do[es] not have a pre-agreed non-inferiority margin with the FDA." But even then, defendant Conterno continued to mislead stockholders by stating that he "continue[s] to have confidence in the Roxadustat

data and in the safety and efficacy profile demonstrated in the Phase 3 program," despite the fact that the sensitivity analyses showed hazard ratios far exceeding a non-inferiority margin of 1.25, rendering FDA approval unlikely.

209. Second, after being told in July 2020 that the FDA believed a "black box" warning would be required for Roxadustat, the Individual Defendants permitted the Company to repeatedly disclose management's "belief" that such a warning would not be necessary and to repeatedly tout the supposed safety profile of Roxadustat. These disclosures were materially misleading because the failed to also disclose that, regardless of management's "belief," the FDA believed the contrary and regardless of management's characterizations of the safety of Roxadustat, the FDA had indicated that it would likely require a "black box" warning which contradicted professions of demonstrated safety.

210. Third, after learning no later than November 2020 that the data submitted to the FDA had been manipulated using post hoc stratification factors, the Individual Defendants concealed the same for five more months, and concealed the extreme negative impact on the results caused by using the pre-specified stratification factors.

211. The Board's failure to adequately oversee the mission critical compliance risks related to the NDA and its follow-on decision to allow misleading disclosures regarding the NDA, communications with the FDA, and the study results

themselves were breaches of fiduciary duty and raise ample reason to doubt the Board's good faith.

212. Thus, demand is excused as to Conterno, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs.

Additional Reasons Demand is Excused

213. At all relevant times, Conterno was the Company's CEO, and therefore was not independent under NASDAQ listing rules. As an employee, Conterno derives substantially all of his income from his employment with FibroGen, thus could not disinterestedly consider a demand for action that might require him to sue the directors that control his continued employment and/or his fellow members of management with whom he works on a day-to-day basis. Moreover, as CEO, Conterno knew or recklessly disregarded the data manipulation that caused the Company to submit inaccurate and/or misleading data in connection with its Roxadustat NDA to the FDA. Conterno personally issued the materially misleading statements and concealed the material facts described herein. As a result, Conterno would be disinterested in a demand regarding his own wrongdoing, and demand is futile as to him.

214. Furthermore, Schoeneck, Edwards, Ho, and Lema also served as members of the Audit Committee at relevant times. As such, they are responsible for the integrity of FibroGen's financial statements. In their capacities as Audit

Committee members, Schoeneck, Edwards, Ho, and Lema reviewed and approved the materially misleading statements and allowed them to be disseminated in FibroGen's SEC filings and other disclosures. Thus, Schoeneck, Edwards, Ho, and Lema breached their fiduciary duties and are not disinterested, and demand is excused as to them.

215. Schoeneck, Henderson, Riggs, and Lema are co-investors in Cibus US LLC, an agricultural company that purportedly engineers a new era of plant breeding techniques using a proprietary technology. Riggs serves as its CEO. Due to their significant long-standing relationships, Schoeneck, Henderson, Riggs, and Lema cannot disinterestedly consider a demand to sue themselves or each other.

FIRST CLAIM

Against the Individual Defendants
for Violations of Section 14(a) of the Exchange Act

216. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

217. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) claims alleged herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these non-fraud claims.

218. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l]."

219. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9.

220. In the exercise of reasonable care, the Individual Defendants should have known that, by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the Proxies were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for stockholder determination in the Proxies, including, but not limited to, election of directors, ratification of an independent auditor, and the

approval (on an advisory basis) of executive compensation.

221. The false and misleading elements of the annual Proxies led to the re-elections of Defendants Conterno, Henderson, Ho, Kearns, Kurkijärvi, Lema, and Schoeneck, allowing them to continue breaching their fiduciary duties to FibroGen.

222. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the Proxies.

223. Plaintiff, on behalf of FibroGen, has no adequate remedy at law.

SECOND CLAIM

Against the Individual Defendants
for Violations of Section 20(a) of the Exchange Act

224. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

225. The Individual Defendants, by virtue of their positions with FibroGen and their specific acts, were, at the time of the wrongs alleged herein, controlling persons of FibroGen and officers and directors who made the false and misleading statements alleged herein within the meaning of § 20(a) of the Exchange Act. The Individual Defendants had the power and influence, and exercised same, to cause FibroGen to engage in the illegal conduct and practices complained of herein.

226. Plaintiff, on behalf of FibroGen, has no adequate remedy at law.

THIRD CLAIM

Against Individual Defendants
for Breach of Fiduciary Duties

227. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

228. The Individual Defendants owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of FibroGen's business and affairs, particularly with respect to issues as fundamental as the accuracy of its publicly reported financial information.

229. The conduct of the Individual Defendants set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company. The Individual Defendants intentionally or recklessly breached their fiduciary duties to protect the rights and interests of FibroGen.

230. In particular, the Individual Defendants knowingly or recklessly made untrue statements and/or permitted the Company's public filings, disclosures, and statements to contain materially untrue statements.

231. As a direct and proximate result of these breaches of their fiduciary obligations, FibroGen has sustained and continues to sustain significant damages, including direct monetary damages, exposure to liability from securities litigation and a loss of goodwill in the capital markets. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

FOURTH CLAIM

Against Defendants Chung, Cotroneo, Kearns, Kurkijärvi, Schoeneck, and Yu
for Insider Trading (Brophy Claim)

232. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

233. As alleged above, Chung, Cotroneo, Kearns, Kurkijärvi, Schoeneck, and Yu are fiduciaries of FibroGen, possessed material non-public information of FibroGen, and used that information improperly to profit from sales of FibroGen stock. When Chung, Cotroneo, Kearns, Kurkijärvi, Schoeneck, and Yu directed the stock sales set forth above, they were motivated to do so, in whole or in part, by the substance of the material non-public information they possessed, and they acted with scienter.

234. When Chung, Cotroneo, Kearns, Kurkijärvi, Schoeneck, and Yu sold their FibroGen stock, they knew that the investing public was unaware of the negative material information that they possessed. They also knew that if the information were disclosed, the market price of FibroGen stock would be significantly lower. Chung, Cotroneo, Kearns, Kurkijärvi, Schoeneck, and Yu timed their stock sales to take advantage of the investing public's ignorance of the concealed material facts and obtain a higher price for the stock they sold. They thereby benefited by misappropriating FibroGen's non-public information.

235. Plaintiff, on behalf of FibroGen, has no adequate remedy at law.

FIFTH CLAIM

Against Individual Defendants
for Unjust Enrichment

236. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

237. By their wrongful acts, violations of law, false and misleading statements, and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense and to the detriment of FibroGen.

238. The Individual Defendants either benefitted financially from the improper conduct, received unjust compensation tied to the false and misleading statements, received bonuses, stock options, or similar compensation from FibroGen tied to the performance or artificially inflated valuation of FibroGen, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct, or sold stock at artificially inflated prices during the Relevant Period.

239. Plaintiff, as a stockholder and a representative of FibroGen, seeks restitution from the Director Defendants and seeks an order from this Court disgorging all profits— including benefits, performance-based, valuation-based, and other compensation—obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary duties.

240. Plaintiff, on behalf of FibroGen, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of FibroGen, demands judgment as follows:

A. Declaring that plaintiff may maintain this action on behalf of FibroGen and that plaintiff is an adequate representative of the Company;

B. Against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties;

C. Directing FibroGen to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect FibroGen and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

1. a proposal to strengthen the Company's controls over financial reporting;

2. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board;

3. a proposal to strengthen FibroGen's oversight of its disclosure procedures;

4. a provision to control insider transactions; and

5. a provision to permit the stockholders of FibroGen to nominate at least three candidates for election to the Board;

D. Extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of FibroGen has an effective remedy;

E. Awarding to FibroGen restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants;

F. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

G. Granting such other and further relief as the Court deems just and proper.

Dated: June 21, 2023

Respectfully submitted,

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